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Protocol

The Effects of Propofol Cardioplegia on Blood and Myocardial Biomarkers of Stress and Injury in Patients With Isolated Coronary Artery Bypass Grafting or Aortic Valve Replacement Using Cardiopulmonary Bypass: Protocol for a Single-Center Randomized Controlled Trial

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Abstract

Background: Despite improved myocardial protection strategies, cardioplegic arrest and ischemia still result in reperfusion injury. We have previously published a study describing the effects of propofol (an anesthetic agent commonly used in cardiac surgery) on metabolic stress, cardiac function, and injury in a clinically relevant animal model. We concluded that cardioplegia supplementation with propofol at a concentration relevant to the human clinical setting resulted in improved hemodynamic function, reduced oxidative stress, and reduced reperfusion injury when compared to standard cardioplegia.

Objective: The Propofol cardioplegia for Myocardial Protection Trial (ProMPT) aims to translate the successful animal intervention to the human clinical setting. We aim to test the hypothesis that supplementation of the cardioplegic solution with propofol will be cardioprotective for patients undergoing isolated coronary artery bypass graft or aortic valve replacement surgery with cardiopulmonary bypass.

Methods: The trial is a single-center, placebo-controlled, randomized trial with blinding of participants, health care staff, and the research team. Patients aged between 18 and 80 years undergoing nonemergency isolated coronary artery bypass graft or aortic valve replacement surgery with cardiopulmonary bypass at the Bristol Heart Institute are being invited to participate. Participants are randomly assigned in a 1:1 ratio to either cardioplegia supplementation with propofol (intervention) or cardioplegia supplementation with intralipid (placebo) using a secure, concealed, Internet-based randomization system. Randomization is stratified by operation type and minimized by diabetes mellitus status. Biomarkers of cardiac injury and metabolism are being assessed to investigate any cardioprotection conferred. The primary outcome is myocardial injury, studied by measuring myocardial troponin T. The trial is designed to test hypotheses about the superiority of the intervention within each surgical stratum. The sample size of 96 participants has been chosen to achieve 80% power to detect standardized differences of 0.5 at a significance level of 5% (2-tailed) assuming equal numbers in each surgical stratum.

Results: A total of 96 patients have been successfully recruited over a 2-year period. Results are to be published in late 2014.

Conclusions: Designing a practicable method for delivering a potentially protective dose of propofol to the heart during cardiac surgery was challenging. If our approach confirms the potential of propofol to reduce damage during cardiac surgery, we plan to design a larger multicenter trial to detect differences in clinical outcomes.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 84968882; <http://www.controlled-trials.com/ISRCTN84968882/ProMPT> (Archived by WebCite at <http://www.webcitation.org/6Qi8A51BS>).

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KEYWORDS

cardiac surgery; anesthetics; cardiopulmonary bypass; ischemia; reperfusion; cardioplegia; aortic valve; coronary artery; troponin; clinical trials, randomized

Introduction

During cardiac surgery with cardiopulmonary bypass (CPB), a cardioplegia (heart-stopping) solution is used to arrest the heart. Although beneficial for the surgical procedure, the oxygen/nutrient deficit and restriction in blood supply (ischemia) can result in myocardial damage and dysfunction. In addition, restoration of oxygenated blood flow (reperfusion) after a period of ischemia can cause further (and often more severe) damage. This is known as ischemia/reperfusion (I/R) injury.

Loss of control over cellular calcium mobilization and the generation of reactive oxygen species (ROS) are known to be key events critical to the induction of I/R damage [1]. Elevated intracellular calcium leads to the destruction of mitochondrial cell membrane integrity [2] and eventual recruitment of macrophages and neutrophils to the area causing further damage to surrounding tissue. There are several sources of ROS generation with all species interacting with numerous cellular targets. ROS attack a wide range of biological molecules resulting in deleterious wide-ranging effects, including attack of the cardiomyocyte [3]. Furthermore, cytosolic calcium loading and the generation of ROS can result in the opening of the mitochondrial permeability transition pore (MPTP). Mitochondrial disruption consequently leads to cardiomyocyte death [1,4].

Strategies to protect the heart during cardiac surgery include interventions that target the mitochondria, such as alteration of cardioplegia temperature, method of delivery and composition, and the use of calcium transport modulators and/or inhibitors of the MPTP [1,5-11]. A number of anesthetic agents have also been implicated in cardioprotection strategies [12-14]. Inhalation anesthetics have been shown to decrease myocardial oxygen demand and contractility [15] and intravenous anesthetics have been shown to exhibit antioxidant effects [16]. Both are reported to play a role in the reduction of the systemic anti-inflammatory response.

Propofol is a general anesthetic widely used for the induction and maintenance of anesthesia during cardiac surgery and for postoperative sedation. In addition to its anesthetic effect, propofol has been reported to confer protection against damage to the myocardium during oxidative stress [17] and reperfusion [18,19]. Various mechanisms have been proposed to explain this cardioprotective effect, including inhibition of plasma membrane calcium channels [20,21], free radical scavenging [22-25], and enhancing antioxidant capacity [26,27].

Furthermore, reports have shown propofol can inhibit the MPTP in isolated mitochondria [28,29], although nonclinical concentrations were employed in these studies.

We have previously published a study describing the effects of propofol on metabolic stress, cardiac function, and injury in a clinically relevant animal model of normothermic cardioplegic arrest and CPB [30]. We were able to conclude that cardioplegia supplementation with propofol at a concentration relevant to the human clinical setting resulted in improved hemodynamic function, reduced oxidative stress, and reduced I/R injury when compared to standard cardioplegia.

The aim of our current trial is to translate propofol supplementation from our animal model to a human clinical setting by investigating the benefits of using propofol as an adjunct to cardioplegia for patients undergoing coronary artery bypass grafting (CABG) or aortic valve replacement (AVR) surgery using CPB. Specific objectives are:

1. To estimate mean differences in biomarkers of cardiac injury and metabolism between groups of participants having isolated CABG with CPB using warm blood cardioplegia with propofol supplementation vs supplementation with placebo.
2. To estimate mean differences in biomarkers of cardiac injury and metabolism between groups of participants having AVR with CPB using cold blood cardioplegia with propofol supplementation vs supplementation with placebo (intralipid).

Methods

Overview

The Propofol cardioplegia for Myocardial Protection Trial (ProMPT) is designed as a single-center, placebo-controlled, randomized trial. Participants, health care staff, and members of the research team involved in data collection or providing health care, except for the perfusionist, are blinded to a participant's allocation.

Trial Population and Recruitment Procedure

Patients undergoing nonemergency isolated CABG or AVR with CPB at the Bristol Heart Institute (BHI) are being invited to participate.

Participants may enter the trial if they are male or female, between 18 and 80 years, having elective or urgent CABG or AVR with CPB, and are able to give full informed consent for

the trial. Patients may not enter the trial if any of the following apply: (1) previous cardiac surgery, (2) combined CABG and AVR, (3) emergency or salvage operation, (4) chronic renal failure requiring dialysis, (5) current congestive heart failure, (6) left ventricular (LV) ejection fraction <30% (ie, poor LV function), (7) allergy to peanuts, eggs, egg products, soybeans, or soy products (these are intralipid ingredients), or (8) participating in another interventional trial.

Potential trial participants are identified from operating theater lists and are sent or handed an invitation letter and information leaflet that has been approved by a NHS Research Ethics Committee (REC). They have at least 24 hours to consider whether to participate. If there is insufficient time to consider taking part, a potential participant is not approached to ask for written informed consent.

After admission to the BHI, patients are seen by a member of the research team who answers any questions, confirms eligibility, and requests and witnesses written informed consent. Details of all patients approached for the trial and reasons for nonparticipation (eg, reason for being ineligible or declining consent) are being documented.

Randomization

Each participant is randomly assigned in a 1:1 ratio within CABG or AVR surgery stratum to standard cardioplegia with either propofol (intervention) or intralipid (placebo) supplementation using a secure, concealed, central Internet-based randomization system (Sealed Envelope Ltd). Standard cardioplegia is warm blood for CABG and cold blood for AVR. Randomization is minimized by diabetes mellitus status, defined as requirement for oral or insulin medication to control blood sugar at the time of admission. A member of the Clinical Trials and Evaluation Unit (CTEU) Bristol who is not involved in data collection or providing health care randomizes a participant shortly before surgery and communicates the allocation to the perfusionist. If a participant is unexpectedly rescheduled, the trial number and randomized allocation is retained.

Intervention and Placebo

Overview

Propofol (Fresenius Propoven 1%) is licensed for the induction and maintenance of anesthesia and is used for these purposes by most cardiac anesthetists at the BHI.

Intralipid emulsion is used as the vehicle for propofol administration; therefore, they have exactly the same consistency and milky appearance. It has been suggested that intralipid is itself cardioprotective (based on recovery of cardiac function in rats) [31], but it does not appear to confer protection against cardiac injury [32]. We wish to test the specific hypothesis that

propofol supplementation is cardioprotective and a recognized mechanism is postulated. For these reasons, intralipid has been chosen as the placebo for this trial.

Propofol is diluted in a 1:5 ratio with 0.9% sodium chloride as recommended by the manufacturer to achieve a working solution of 2000 µg/mL. Intralipid is diluted in the same manner.

Propofol and intralipid for use in the trial are labeled and dispensed by the Bristol Royal Infirmary (BRI) pharmacy in accordance with Good Clinical Practice (GCP).

Standard Cardioplegia Composition and Delivery

Calafiore warm blood cardioplegia (for CABG): A 60 mL syringe is prepared with 20 mL of 15% potassium chloride (2 mmol K⁺/mL) and 5 mL of 50% magnesium sulfate (2 mmol Mg²⁺/mL), resulting in a ratio of 4:1 potassium:magnesium in the syringe driver. A roller pump draws oxygenated blood from the oxygenator and the potassium–magnesium mixture is added by syringe pump downstream. Intermittent antegrade delivery is used according to local protocol.

Cold blood cardioplegia (for AVR): A 500 mL prebagged solution of Harefield Hospital Formulation (IVEX Pharmaceuticals Ltd, Larne, Northern Ireland, UK) is used. A roller pump draws up oxygenated blood from the oxygenator and the cardioplegia solution is added in a 4:1 blood:cardioplegia ratio. Cold cardioplegia is given at a temperature of approximately 4°C and by either antegrade or retrograde delivery (or a mixture of both) according to local protocol.

Anesthetic Management and Supplementation of Cardioplegia

Anesthetic management adheres strictly to a locally agreed protocol (see [Multimedia Appendix 1](#)) and all other aspects of the patient's preoperative and postoperative management are in accordance with existing protocols in use in the BHI.

For CABG procedures, propofol (or intralipid) is added to the cardioplegia by attaching an additional syringe pump to the line, downstream of the blood oxygenator ([Figure 1](#)). For AVR procedures, propofol (or an equivalent volume intralipid) is added directly to a 500 mL bag of 4:1 cardioplegia solution ([Figure 2](#)).

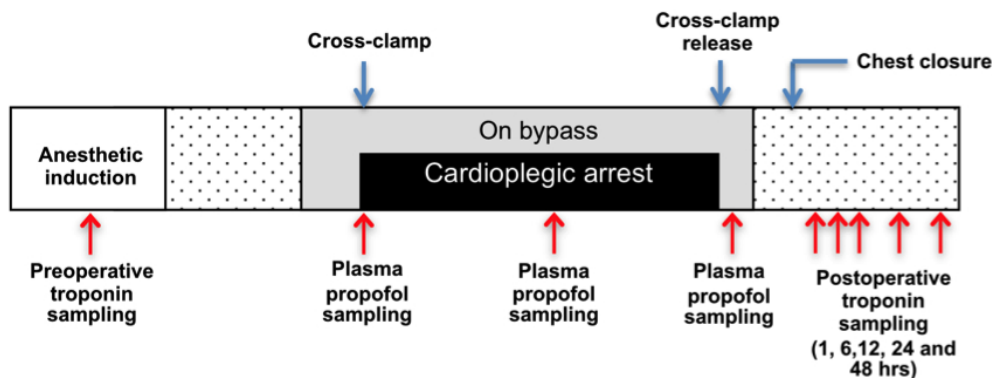
For both intervention groups, the cardioplegia solution (blood–cardioplegia mix) has a final concentration target of 6 µg/mL of supplemented propofol. This concentration is significantly below the level routinely observed in the circulation during induction of anesthesia for cardiac surgery, but higher than during maintenance of anesthesia when cardioplegia is administered (ie, a concentration to which the myocardium is routinely exposed).

Primary Outcome

The primary outcome is myocardial injury, assessed by measuring myocardial troponin T in serum from blood samples collected preoperatively and at 1, 6, 12, 24, and 48 hours after

chest closure (Figure 3). Although absolute times of sampling after reperfusion could vary between participants, blinding of the intervention prevents any systematic difference between groups.

Figure 3. Measurement of myocardial injury and propofol concentration. The primary outcome is myocardial injury, assessed by measuring myocardial troponin T in serum from blood samples collected preoperatively and at 1, 6, 12, 24, and 48 hours after chest closure. The concentration of plasma propofol is measured in blood samples collected from the cardioplegia/bypass circuit immediately before aortic cross-clamping, once during cardioplegia (after blood–cardioplegia mixing), and 10 min post cross-clamp release.



Secondary Outcomes

Data are collected to characterize the following secondary outcomes:

1. Myocardial ischemic stress assessed using biopsies taken from left and right ventricles immediately before aortic cross-clamping and 10 minutes after cross-clamp release. Gene expression and cellular changes associated with stress and injury-signaling pathways are to be studied in a small subset of biopsies using metabolite/RNA extracts.
2. Systemic metabolic stress assessed by measuring lactate in blood samples collected preoperatively and 1, 6, 12, 24, and 48 hours after chest closure.
3. Blood pH measured by using the blood samples collected preoperatively and 1, 6, 12, 24, and 48 hours after chest closure.
4. Renal function assessed by measuring creatinine in serum from blood samples collected preoperatively and 1, 6, 12, 24, and 48 hours after chest closure.
5. The concentration of plasma propofol measured in blood samples collected immediately before aortic cross-clamping, once during cardioplegia (after blood–cardioplegia mixing), and 10 minutes after cross-clamp release (Figure 3). Blood is taken from the cardioplegia/bypass circuit.
6. Length of intensive care unit (ICU) / high-dependency unit (HDU) stay.
7. Clinical outcomes and serious adverse events (SAEs), such as serious postoperative morbidity (eg, myocardial infarction, permanent stroke, renal failure defined as new need for hemodialysis) and death from any cause. Case report forms used for data collection specify 26 SAEs that are anticipated after cardiac surgery.
8. Patient health status monitored using customized questionnaires administered preoperatively and completed

by participants as a postal questionnaire 3 months postoperatively. Also, CABG and AVR patients are asked to complete the Coronary Revascularisation Outcome Questionnaire (CROQ) [33] and the Minnesota Living with Heart Failure (MLHF) Questionnaire [34], respectively. The EQ-5D health questionnaire is administered preoperatively and all participants complete this again at 3 months as part of the postal questionnaire.

The primary outcome is myocardial injury, assessed by measuring myocardial troponin T in serum from blood samples collected preoperatively and at 1, 6, 12, 24, and 48 hours after chest closure. The concentration of plasma propofol is measured in blood samples collected from the cardioplegia/bypass circuit immediately before aortic cross-clamping, once during cardioplegia (after blood–cardioplegia mixing), and 10 minutes after cross-clamp release.

Sample Size

The trial is designed to test hypotheses about the superiority of the intervention.

A sample size of 96 has been chosen to enable the trial to detect a standardized difference of 0.5 between the propofol-supplemented and placebo groups, with 80% power at a significance level of 5% (2-tailed) within each surgical stratum. The target difference of 0.5 standard deviations is of moderate magnitude [35], is consistent with our experience of many of these outcomes in previous research to evaluate other cardiac surgery interventions, and is appropriate for an early phase trial. Estimation of the power of the trial assumed that the biomarkers, including the primary outcome, are measured at baseline and 5 times after the intervention and that the correlations between outcomes measured at baseline and after

intervening and between postintervention outcomes measured on multiple occasions are 0.5.

Statistical Analysis

Analyses will be based on the intention-to-treat principle, and will use data from all patients randomized (ie, the analyses will use the complete dataset). Continuous outcomes will be analyzed by regression modeling, transforming data logarithmically if required and adjusting for baseline values where available, and using mixed models for repeated measures. Mixed models allow all patients with data to be included in the analysis; that is, partial missing data (assumed missing at random) is permitted. Prerandomization and subsequent values will be modeled jointly, in preference to the prerandomization value being modeled as a covariate, to avoid the need either to exclude cases with missing preoperative measures or to impute missing preoperative values. Interactions between treatment and time will be examined and, if significant at the 5% level, results will be reported separately for each postoperative time point; otherwise, an overall treatment effect will be reported. Findings will be reported as effect sizes with 95% confidence intervals. Time in ICU/HDU will be analyzed as time-to-event data using Cox regression modeling.

The trial is not powered to detect differences in clinical outcomes and their frequencies will be tabulated descriptively in accordance with guidelines for reporting randomized controlled trials (RCTs) [36].

We do not have a prior expectation that the effect of propofol supplementation will differ by operation, but we will test for this possibility by fitting a treatment by surgery type interaction. If the interaction is statistically significant, surgery-specific effects will be reported along with the results of the interaction test. If, as anticipated, the interaction is not statistically significant at the 10% level, the overall treatment effect will be reported. Similarly, we will test the interaction of propofol supplementation with diabetic status and effects specific to diabetic status will be estimated if this interaction reaches 10% statistical significance.

The primary analysis will take place when follow-up is complete for all recruited patients. No interim analysis is planned.

Ethical Approval and Clinical Trial Authorization

The West Midlands REC approved the trial protocol on the November 16, 2009. The Medicines and Healthcare products Regulatory Agency (MHRA) granted clinical trial authorization on December 11, 2009.

Adverse Events

Adverse events (AEs) will be recorded and reported according to University Hospitals Bristol NHS Foundation Trust and MHRA guidelines. In cardiac surgery, postoperative transient complications are expected and are not infrequent. The research team is required to notify the sponsor about deaths and unexpected nonfatal SAEs. Unexpected events are those not listed in the trial protocol or on the case report forms. The sponsor will inform the research team which SAEs should be reported to the REC and/or MHRA. Data on AEs are being

collected from randomization for the duration of the participant's postoperative hospital stay and for the 3-month follow-up period.

Measures to Reduce the Risk of Bias

The trial includes several features designed to minimize the risk of bias. Concealed randomization will prevent selection bias. Blinding of the research team, clinical staff responsible for caring for patients (surgeons, anesthetists, and nurses), and participants will minimize performance and detection biases. Moreover, outcome measures have been defined as far as possible on the basis of objective criteria. An independent laboratory technician, without knowledge of treatment allocation, will measure biochemical markers.

The patient information leaflet and the process of obtaining informed consent describes the uncertainty about the effects of cardioplegia supplementation with propofol. Therefore, in the event of inadvertent unblinding of a participant, he or she should not have a strong expectation that either method should lead to a more favorable result.

The trial will be analyzed on an intention-to-treat basis (ie, outcomes will be analyzed according to the treatment allocation), irrespective of future management and events, and every effort will be made to include all randomized patients. The fact that trial recruitment is from a single center and coordination is by a UK Clinical Research Collaboration (UKCRC)-registered trials unit on site should promote the completeness of follow-up. Blood samples may be missed at some time points for some patients if their sampling times occur outside the working hours of the research team. In these instances, reliance is placed on the cooperation of ICU nursing staff for sample collection. When samples are missing, we will assume that they are missing at random (see Statistical Analysis) and will allow any participants with at least 1 sample to be included in the analysis.

Dissemination

The ProMPT trial is a novel trial to assess the hypothesis that propofol supplementation of cardioplegia will give better myocardial protection. If this hypothesis is confirmed, we will design a larger trial to test the effect of propofol supplementation on clinical outcomes (eg, postoperative complications).

We have used broad eligibility criteria for the trial and expect the findings to apply to almost all patients undergoing standard CABG or AVR using CPB. The findings will be disseminated through usual academic channels (ie, presentation at international meetings, peer-reviewed publications, and through patient organizations and newsletters to patients, where available). Because propofol is widely available in the acute care setting and is relatively inexpensive, there should be few obstacles to adoption. We do not anticipate that the findings will be commercially exploitable.

Results

Patients have been successfully recruited over a 2-year period. Results are to be published in late 2014.

Discussion

Contrary Evidence

Despite numerous reports supporting a cardioprotective effect of propofol during surgery [17-19,37], there is some evidence to the contrary. For example, studies comparing the volatile anesthetic sevoflurane with propofol for anesthesia during CABG surgery reported protection to be conferred by sevoflurane only [15,38]. This inconsistency may be explained in part by the chosen dose regimen because the cardioprotective effect of propofol has been shown to be dose dependent [19]. Clinical benefits appear to be more evident at higher doses [39] with a maintenance dose of approximately 4.2 µg/mL attenuating postoperative cellular damage and improving clinical outcome in patients undergoing CABG with CPB [40]. This dose has also been shown to confer significant cardioprotection against global ischemia in rats when used as an adjunct to warm or cold cardioplegia [30,32]. The underlying mechanism of protection is independent of any protection conferred by cardioplegia and hypothermia alone [41]. In addition, the intralipid emulsion used as a vehicle for propofol administration exhibits no protection against cardiac injury [32].

Propofol Delivery and Stability in Cardioplegia Solution

One of the major challenges of this trial was to develop a method to deliver a specific dose of propofol/intralipid to the heart during surgery. Although delivering as an adjunct to cardioplegia was the most practicable approach, differences in the temperature and method of delivery of cardioplegia for CABG and AVR procedures had to be addressed. In addition, because propofol had not been used as an adjunct to cardioplegia in the human clinical setting before this trial, it was necessary to determine the occurrence and extent of any physical or physiochemical changes to propofol or intralipid when mixed with cardioplegia solution and 0.9% sodium chloride. The Fresenius Kabi Stability Assessment Unit at Cardiff University performed pH, visual, microscopic, and particle size distribution analysis of relevant combinations of samples at time points ranging from 0 to 24 hours. Evidence of instability was found in the propofol-containing samples after 8 hours. Therefore, a

period of 6 hours was deemed a reasonable, safe period within which to use the trial solutions after they had been made.

Supplementation Concentration

Propofol maintenance during CPB is common practice at the BHI. An infusion rate of 33 to 100 µg/kg/min (equating to 1.98-6 mg/kg/h) is used resulting in a circulating blood propofol concentration of between 1.3 and 3.6 µg/mL.

The trial has adopted a pragmatic approach, giving anesthetists the option to continue with this practice, resulting in baseline concentrations of up to 3.6 µg/mL of propofol for placebo arm participants. To ensure at least a doubling of the propofol concentration between placebo and intervention participants, anesthetists are asked to cap their usage of propofol during maintenance to a 3 µg/mL where possible. A 3 µg/mL blood propofol concentration is well under the dose required for clinical benefit [39]. Our supplementation concentration was set at 6 µg/mL to ensure that a potentially cardioprotective dose of between 6 and 9 µg/mL was achieved in patients allocated to the intervention arm.

The proposed maximum dose of 9 µg/mL does not exceed the level routinely observed in the circulation during induction of anesthesia for cardiac surgery (ie, a safe concentration to which the myocardium is routinely exposed).

Propofol clearance follows a 3-compartmental open model, with a first exponential phase half-life of approximately 1.6 to 4.0 minutes [42]. A short half-life and rapid plasma distribution of propofol results in fast onset and short duration of propofol action. Very little of the supplementary propofol remains in the circulation when the next dose of cardioplegia is administered. Hence, it is exceptionally unlikely that any AEs could be attributed to propofol supplementation postoperatively.

Designing a practicable method for delivering a potentially protective dose of propofol to the heart during cardiac surgery has been challenging, but recruitment has been steady and straightforward. If our approach confirms the potential of propofol to reduce damage to the heart during cardiac surgery, we will apply for funding to carry out a larger multicenter trial powered to detect a difference in a primary clinical outcome.

Acknowledgments

The ProMPT trial is part of a program of research on improving myocardial protection during CPB, carried out under the auspices of the National Institute for Health Research (NIHR), Bristol Cardiovascular, Biomedical Research Unit. ProMPT is sponsored by the University Hospitals Bristol NHS Foundation Trust. All surgery is performed at the BHI. The authors would like to make special thanks to Dr AG Coslett, Dr R Price-Davies, and SJ Rose from the Fresenius Kabi, Cardiff University Stability Assessment Unit for their work on determining the stability of the intervention/placebo proposed in this trial.

Authors' Contributions

All authors have read and approved the final manuscript. Specifically, MSS and GA conceived of the trial and participated in the protocol design. BR and CR designed the protocol, edited the manuscript for key intellectual content, and will coordinate/perform the statistical analysis. JH participated in the protocol design and specified the anesthetic procedure. RD and EN participated in the protocol design and specified the perfusion procedures. ZP drafted the manuscript, participated in protocol design, and has coordinated the trial. SB has assisted in trial coordination. AB is the principal investigator, helped conceive the trial, and participated in the protocol design.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Anesthetic protocol.

[[PDF File \(Adobe PDF File\), 150KB - resprot_v3i3e35_app1.pdf](#)]

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Abbreviations

AE: adverse event

AVR: aortic valve replacement

BHI: Bristol Heart Institute

BRI: Bristol Royal Infirmary
CABG: coronary artery bypass grafting
CPB: cardiopulmonary bypass
CTEU: Clinical Trials and Evaluation Unit
GCP: Good Clinical Practice
HDU: high-dependency unit
ICU: intensive care unit
LV: left ventricular
MHRA: Medicines and Healthcare products Regulatory Agency
MLHF: Minnesota Living with Heart Failure
MPPT: mitochondrial permeability transition pore
NIHR: National Institute for Health Research
ProMPT: Propofol cardioplegia for Myocardial Protection Trial
REC: Research Ethics Committee
ROS: reactive oxygen species
SAE: serious adverse event
UKCRC: UK Clinical Research Collaboration

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Original Paper

The Nurse-Based Age Independent Intervention to Limit Evolution of Disease After Acute Coronary Syndrome (NAILED ACS) Risk Factor Trial: Protocol for a Randomized Controlled Trial

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Abstract

Background: Secondary prevention after acute coronary syndrome (ACS) is essential to reduce morbidity and mortality, but related studies have been fairly small or performed as clinical trials with non-representative patient selection. Long-term follow-up data are also minimal. A nurse-led follow-up for risk factor improvement may be effective, but the evidence is limited.

Objective: The aims of this study are to perform an adequately sized, nurse-led, long-term secondary preventive follow-up with inclusion of an unselected population of ACS patients. The focus will be on lipid and blood pressure control as well as tobacco use and physical activity.

Methods: The study will consist of a randomized, controlled, long-term, population-based trial with two parallel groups. Patients will be included during the initial hospital stay. Important outcome variables are total cholesterol, low-density lipoprotein (LDL) cholesterol, and sitting systolic and diastolic blood pressure. Outcomes will be measured after 12, 24, and 36 months of follow-up. Trained nurses will manage the intervention group with the aim of achieving set treatment goals as soon as possible. The control group will receive usual care. At least 250 patients will be included in each group to reliably detect a difference in mean LDL of 0.5 mmol/L and in mean systolic blood pressure of 5 mmHg.

Results: The study is ongoing and recruitment of participants will continue until December 31, 2014.

Conclusions: This study will test the hypothesis that a nurse-led, long-term follow-up after an ACS with a focus on achieving treatment goals as soon as possible is an effective secondary preventive method. If proven effective, this method could be implemented in general practice at a low cost.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 96595458; <http://www.controlled-trials.com/ISRCTN96595458> (Archived by WebCite at <http://www.webcitation.org/6RlyhYTYK>).

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KEYWORDS

acute coronary syndrome; myocardial infarction; secondary prevention; cardiovascular disease; randomized controlled trial

Introduction

Background

Clinical trials have identified several treatments with proven secondary preventive efficacy after an acute coronary syndrome (ACS) [1]. Implementation of this knowledge, however, faces a number of obstacles and has been more difficult than anticipated [2] for a number of possible reasons. Among these, clinical trials typically include selected populations with lower age and less comorbidity compared with patients in routine clinical practice. In addition, trials generally are rigorously performed during a fairly short period of time, while the clinical environment is complex and difficult to control and the treatment perspective often spans many years. In secondary prevention these difficulties have led to failures in terms of treatment goals and consequently failure in risk reduction [3].

To simplify secondary preventive follow-up procedures while also retaining a high level of treatment adherence, different strategies of telephone support have been evaluated [4-6]. Despite rigorous protocols, ambitious patient information packages, and frequent patient support, the results in terms of reduction of risk factor levels have been modest [7,8]. To some extent, this outcome may be explained by improvements in general care against which intervention results are compared. However, the published secondary preventive trials using telephone support have several weaknesses, including a low proportion of included patients relative to the target population [5,6]. Other weaknesses are age limits, extensive protocols requiring an alert patient, recruitment from selective secondary prevention programs, and exclusion because of comorbidity. Furthermore, a rapid routine intended to allow for prescription changes for lipid and blood pressure control to achieve treatment goals as soon as possible has mostly not been used. Moreover, low-risk patients have been included with a 12-month mortality rate around 2% [7,8]. Thus, more research in this area is needed.

Study Objective

To improve secondary prevention, we have designed a trial with several important components. First, all patients after an ACS will be considered for inclusion regardless of age, and this population-based design will include all residents in the county of Jämtland, Sweden. Second, a maximally simplified, nurse-based, telephone follow-up protocol will be used, which will minimize resources needed as well as patient exclusions and make the methodology easy to implement. Third, a routine for prompt medication adjustment will be used to reach set treatment goals as quickly as possible. Finally, a long-term follow-up is planned with risk factor evaluation after 12, 24, and 36 months.

Hypothesis

We hypothesize that in ACS patients, this nurse-based, telephone follow-up will reduce risk factor levels more effectively than usual care.

Methods

Trial Design

This study is planned as a randomized, controlled trial with two parallel groups and an allocation ratio of 1:1.

Ethical and Research Governance Approval

Ethics approval has been received from the Ethics Committee, Umea University (09-142M). This paper presents the design of the study according to CONSORT requirements [9].

Participants

All patients living in the county of Jämtland, Sweden, who were hospitalized with a diagnosis of myocardial infarction or unstable angina will be assessed for inclusion. Östersund Hospital is the only hospital in the county, and all patients, those in terminal care excluded, with symptoms of a suspected ACS are referred for diagnostic evaluation. It is a rural catchment area with a population of approximately 125,000 inhabitants. A routine for identification of all patients in the hospital with a possible ACS has been established in previous studies, and during a 3-month test period, the study nurses identified all patients with a final ACS diagnosis. In the present study, an ACS was defined as myocardial infarction type 1 or unstable angina with electrocardiogram changes (ST depression or T wave changes) suggesting myocardial ischemia. All patients with the physical and mental capacity to communicate by telephone will be eligible, which means that those with deafness or dementia will be excluded. The other exclusion criteria are severe, often terminal, disease and participation in another ongoing trial.

Interventions

All eligible patients will be informed about the study and asked to give written informed consent. They will receive standard information about ACS concerning pathophysiology and risk factors according to established clinical practice during their hospitalization. They will also be offered a follow-up visit to a cardiology nurse and an outpatient follow-up according to usual care.

A study nurse will contact patients randomized to the intervention group by phone 1 month after discharge. Before the call, a blood sample for lipids will be taken and a standardized blood pressure control performed. Blood pressure will be measured after 5 minutes in the sitting position and after 1 minute standing. A district nurse will perform the tests; for patients in the intervention group living close to the hospital, a study nurse will do the testing. Cardiac symptoms and self-reported adherence with medication will be recorded. During the call, the patient will be informed about the test results and whether a change in medication is necessary. Tobacco use, physical activity, and dietary habits will be discussed. Smoking cessation will be encouraged and supported. Physical activity of moderate intensity 30 minutes or more on most days of the week will be encouraged but also adjusted to the individual patient's capacity. Dietary advice to reduce saturated fat and increase fruit and vegetable intake will be given. If the patient's cholesterol or blood pressure values are above target, medication

will be adjusted after contact from a study physician. Tests will be repeated within approximately 4 weeks, and further adjustments made if necessary until target values are reached or no further changes can be considered realistic. The same routine, with an Hb1C test added, will be applied after 12, 24, and 36 months. The patient's motivation to follow instructions will be assessed.

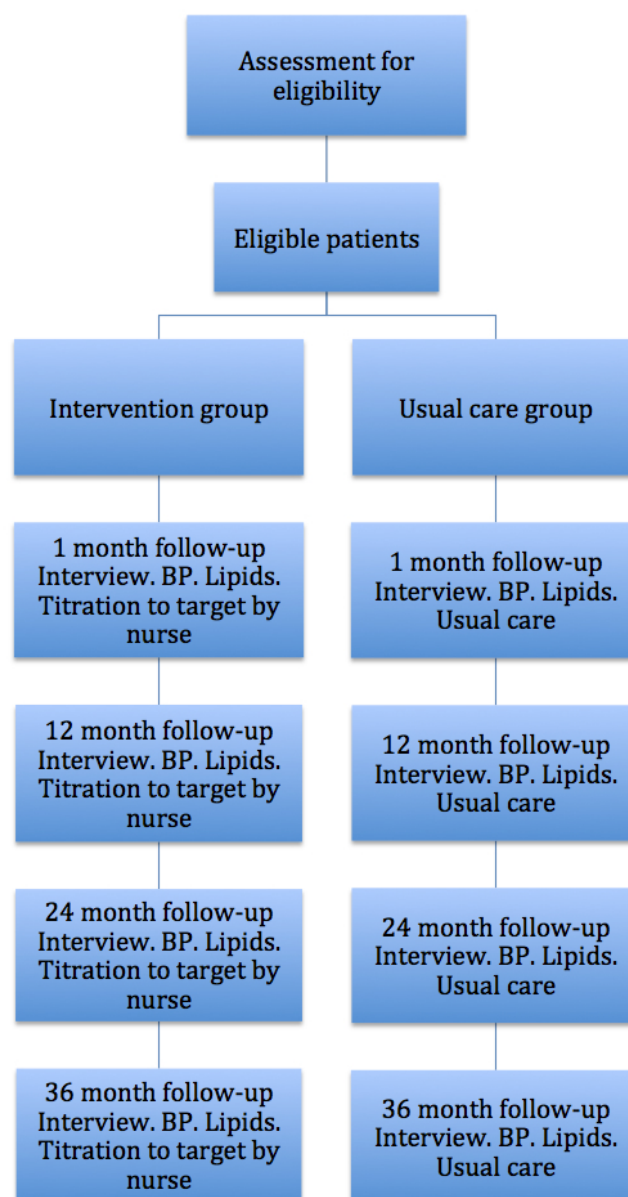
The target values are systolic blood pressure <140/<90 mmHg, total cholesterol <4.5 mmol/L, and low-density lipoprotein (LDL) cholesterol <2.5 mmol/L (optionally <1.8 mmol/L in patients at very high risk, eg, who have diabetes) [10,11].

Patients randomized to the usual care group will also be contacted by phone 1 month following discharge after blood pressure and lipid profile measurements. Cardiac symptoms,

self-reported compliance, tobacco use, and physical activity will be recorded. The treating physician, usually a general practitioner, will provide all medical care and receive the test results (lipid profile and blood pressure), and no additional intervention will be given as a result of participation in the study. The scheduled controls of blood pressure and lipids in the study will be additive to the usual follow-up performed by the general practitioner. The same routine, with an Hb1C test added, will be applied after 12, 24, and 36 months (Figure 1). Participation in the study will otherwise not affect the standard of care in the usual care group.

The number of visits to the patient's treating physician as well as visits to a nurse will be recorded to develop a picture of the number of medical assessments in the control and intervention groups.

Figure 1. Study flow chart (BP=blood pressure).



Outcomes

Outcomes will be measured after 12, 24, and 36 months of follow-up. Outcome variables are total cholesterol, LDL cholesterol, and sitting systolic and diastolic blood pressure as well as the proportion of patients achieving the set target for these variables. Standing systolic and diastolic blood pressure, smoking rates, the proportion of patients treated with different secondary preventive drugs, diabetes control by Hb1C, and change in body mass index (BMI) and physical activity will also be measured. The LDL value at 36 months will be analyzed as the primary outcome. Analyses of the secondary outcomes will be exploratory. Blood pressure measurements are standardized as described above, and LDL values are calculated from the serum concentrations of cholesterol and fasting triglycerides using the Friedewald formula. Smoking (yes/no) and physical activity (duration/week) are self reported. Deaths are available in the hospital records and will be recorded to detect any survival difference between groups.

Sample Size

A difference between groups in mean LDL of 0.5 mmol/L and in mean systolic blood pressure of 5 mmHg is considered clinically relevant and requires study groups of approximately 200 participants to be reliably detected (alpha .05, two-tailed, power 80%). Study groups of at least 250 participants are planned to allow for drop-outs. This sample size is also adequate for detection of clinically meaningful group differences in smoking rates (10%), proportion reaching treatment goals (10%), change in BMI (1.0), and change in physical activity (10%, proportion in a given activity level), calculated with two-tailed alpha .05, power 80%.

Randomization

The random allocation sequence will be computer generated in blocks of four and stratified for sex and type of ACS (unstable angina or myocardial infarction). A sealed, colored envelope will have a serial number on the outside and a folded sheet of paper inside with the group allocation written on it, which will be impossible to read from the outside. The study coordinators will enroll participants and assign them to interventions in order according to the serial number. The random allocation sequence will be computer generated by the study manager, who is not involved in the randomization process.

Statistical Methods

Mean values of blood pressure and lipid variables in the intervention and control groups will be compared using the *t* test for independent groups. Proportions will be compared using the chi-square test. The primary analysis will be performed according to the intention-to-treat principle using a linear regression model adjusting for sex and type of ACS. The adjustment is made to reflect the stratified randomization process. Per protocol analyses will also be performed. Secondary outcomes will be analyzed using the primary analysis model when continuous, and a logistic regression model, adjusting for the same covariates, when outcomes are binary. To assess indications of differential treatment effects across subgroups (ie, age, sex, comorbidity, level of education, and social classification), tests for interaction will be performed, although

this aim is secondary because the study is not powered for this particular purpose. Adjustment for relevant baseline covariates will be performed in additional exploratory analyses of primary and secondary outcomes to evaluate the effect of possible baseline imbalance. All tests will be two-sided, and a *P* value of <.05 will be considered significant.

Results

The study is ongoing and recruitment of participants will continue until December 31, 2014.

Discussion

Summary

Different approaches have been used to recruit patients for secondary prevention studies after an ACS. Some have involved contacting patients participating in rehabilitation programs [5], and others have identified patients with a previous diagnosis of coronary artery disease [6]. To avoid selection bias, a population-based approach is preferable and is the only way to obtain a reliable estimate of the proportion of excluded patients. Enrollment of the patients immediately after an acute event is probably the best way to achieve a high participation rate. This study covers all patients in a Swedish county, who will be eligible for inclusion after an ACS, thus avoiding selection bias. Thus, the study population will include even very old and very sick ACS patients, who are usually not part of randomized ACS studies. Their ability to participate in secondary prevention programs and their tolerability of medication when attempting to achieve set treatment goals are of great interest because these factors could have significant consequences for health economics and morbidity and mortality rates. The immediate recruitment and the logistics for including each and every ACS patient will show the true proportion of possible participants in the secondary preventive program.

A randomized design is necessary to reliably evaluate the effect of the intervention. Some investigators use a prospective cohort design, which makes it difficult to draw conclusions in terms of efficacy, particularly if the drop-out rate is high [12]. The design of the present study means that patients in the usual care group will be contacted by the study nurses to collect data about risk factors. This step adds a certain interference and possibly improvement in usual care but cannot be avoided if the results of the two groups are to be compared. The standard of care that is achieved in the intervention and control group can be assessed by comparing lipid and blood pressure values as well as other risk factor results with the corresponding values in other ACS populations.

We use an associated study physician for the intervention group to obtain immediate decisions about more qualified treatment changes. Based on the results of previous studies, rapid treatment decisions by someone directly involved in the study are related to more effective risk factor control [13].

The duration of follow-up has varied substantially among studies [8,14]. A follow-up period of at least 12-24 months seems necessary to evaluate the intervention during a clinically relevant period of time.

Different treatment goals for lipids and blood pressure have been used in different trials, but an LDL goal of <2.5 mmol/L and a blood pressure goal of <140/<90 are common [8]. These goals correspond well to recent American Heart Association /American College of Cardiology Foundation guidelines [15]. An option to treat lipids more aggressively in very high-risk patients with an LDL goal <1.8 mmol/L is included but given a lower class of recommendation. An LDL goal of <1.8 mmol/L in patients at very high cardiovascular disease risk is recommended in the recent European Society of Cardiology guidelines [16]. However, hard endpoint data from clinical trials using defined treatment goals are still lacking.

Secondary prevention after an ACS needs to be improved and to include a larger proportion of the patients. Importantly, the treatment goals need to be maintained over the long term. Even in trials that largely rely on telephone follow-up, the proportion of the target population eventually included has so far been small [5,6,17].

Conclusion

The present trial is designed to be simple and to require a minimum of health care resources while simultaneously giving patients an effective secondary prevention. The methodology can be widely generalized and makes the inclusion of a majority of the ACS population possible, regardless of the health care system.

Acknowledgments

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Authors' Contributions

TM conceived and designed the research and drafted the initial manuscript. FB, AG, DH, SJ, UK, AS, and AU were involved in the critical revision for important intellectual content, participated in the final design, and assisted with writing the final manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ACS: acute coronary syndrome
BMI: body mass index
LDL: low-density lipoprotein

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Original Paper

Effect of Web-Based Messages on Girls' Knowledge and Risk Perceptions Related to Cigarette Smoke and Breast Cancer: 6-Month Follow-Up of a Randomized Controlled Trial

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Abstract

Background: Evidence indicating an association between cigarette smoke exposure and an increase in breast cancer risk highlights the need for health messages that aim to prevent smoking initiation and reduce secondhand smoke (SHS) exposure among adolescent girls.

Objective: This study aimed to evaluate the efficacy of targeted gender-sensitive, breast cancer-specific, Web-based messages about the increased risk of breast cancer associated with cigarette smoke exposure. Outcomes assessed 6 months postmessage delivery included nonsmoking adolescent girls' knowledge of the link between cigarette smoke exposure and breast cancer, perceptions of breast cancer risk associated with cigarette smoke, smoking behavior and intentions, and stage of change related to avoidance of secondhand smoke.

Methods: A prospective randomized controlled trial was used to compare standard (control) messages with targeted gender- and Aboriginal status-sensitive, breast cancer-specific (intervention) messages. Messages were delivered online to 618 nonsmoking girls, aged 13 to 15 years, clustered in 74 Canadian secondary schools.

Results: Compared with the control group, girls in the intervention group were significantly more likely to report that breast cancer is an illness caused by cigarette smoke (adjusted relative risk [ARR] 1.33, 95% CI 1.05-1.68) and to agree that exposure to SHS increases their risk of breast cancer (ARR 1.10, 95% CI 1.02-1.20). No significant effects were observed for a change in smoking status, intention to try smoking, or stage of change related to avoidance of SHS.

Conclusions: Compared with standard messages, targeted gender-sensitive, breast cancer-specific messages had a stronger influence on girls' knowledge and perceived risk of cigarette smoke exposure as a risk factor for breast cancer. Brief information-based interventions delivered over the Internet have the potential to provide effective health promotion that could be broadly disseminated and lead to long-term effects on girls' knowledge and risk perceptions about cigarette exposure and breast cancer.

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KEYWORDS

secondhand smoke; breast cancer; Web-based health promotion; adolescents

Introduction

Recent evidence indicates that cigarette smoking and secondhand smoke (SHS) exposure are associated with an increase in premenopausal breast cancer risk [1-7]. In 2009, the Canadian Expert Panel on Tobacco Smoke and Breast Cancer concluded that, based on epidemiologic and toxicological studies, the associations between cigarette smoking and breast cancer, as well as between long-term regular SHS exposure and premenopausal breast cancer “are consistent with causality” [2-8]. Since the Canadian report, 2 large cohort studies—the Nurses’ Health Study that examined 8772 breast cancer cases [7] and a Norwegian cohort study examining 7490 cases [9]—clearly demonstrated that the critical window of exposure is from menarche to first childbirth, and confirmed what Ha et al had discovered in a smaller US cohort study in 2007 [10]. In all 3 of these cohort studies a clear dose-response relationship was evident—the longer females smoked between menarche and first childbirth, and the more they smoked during that time period, the greater their risk for breast cancer. Additionally, smoking after first childbirth did not increase risk in these studies [7,9]. More recently, analyses from 2 large cohort studies with lifetime assessments of SHS indicated increased breast cancer risk associated with high lifetime SHS exposure [3,11].

The increased risk of premenopausal breast cancer associated with smoking and SHS, especially exposure between menarche and first childbirth, has direct implications for breast cancer prevention strategies. In a recent Canadian survey, 10% of youth in grades 10-12 self-identified as current smokers [12]. The prevalence of youth who had ever tried smoking a cigarette was 16% in grades 6-9 and 40% in grades 10-12, with the average age of tobacco initiation among Canadian girls in 2011 being 13 years [12]. Further, an estimated 22% of youth in grades 5-12 were exposed daily or almost daily to SHS in their homes [12,13]. Although research identifying cigarette exposure as a modifiable risk factor for breast cancer was published in 2009, few interventions have aimed to increase awareness of the causal link between cigarette smoke and increased risk of breast cancer in premenopausal women [14].

From a cancer prevention perspective, targeting interventions toward adolescent girls is particularly important because it is during periods of breast development that cigarette smoke exposure appears to increase the risk of breast cancer. The potential effectiveness of targeting tobacco control messages that highlight the benefits of reducing breast cancer risk toward adolescent girls is also supported by health behavior theory. The pubertal period is marked by heightened awareness of physical (ie, breast development) and psychological (ie, gendered social identity) changes, and can therefore be exploited as a teachable moment for breast cancer prevention [15]. As such, targeted messages linking breast cancer risk with tobacco exposure may hold distinct advantages over general messages about smoking and cancer that youth may dismiss because they perceive the risk to be associated with a distant consequence that is not relevant to their immediate health [16]. In designing

breast cancer-specific messages targeting adolescent girls that address the risk of tobacco exposure, it has been recommended that interventions link tobacco exposure to breast cancer in ways that are gender-sensitive, in that messages are relevant and appropriate for girls in this age group (eg, avoiding sexualized images of breasts), reflect the context of tobacco use within youths’ social world, and be attuned to gender-related issues (eg, emerging femininities and girls’ peer relations) [14].

Several meta-analyses and systematic reviews indicate that targeted messages are more persuasive than generic messages, and lead to greater improvements in outcomes including behavioral intentions, behavior change, and attitudes [17-22]. The potential benefit of using targeted gender-sensitive messaging in the context of a teachable moment is also supported by the results of a qualitative study recently conducted by our group. The findings of this study indicated that adolescents seemed to be more receptive to gender-sensitive messages about the relationship between cigarette smoke and breast cancer than they were to standard or putatively gender-neutral messages [23].

The rapid expansion in adolescents’ use of the Internet has led to the characterization of the Internet as an ideal channel for risk factor screening (eg, cigarette smoke exposure and/or smoking behavior) that can be coupled with the delivery of targeted health promotion interventions to reduce cigarette smoke exposure [24]. Digital technology-based interventions can be rapidly disseminated, and can include interactive components that engage youth [25]. Recent studies also indicate that youth-friendly, socially-oriented, and Web-based health messages and interventions can positively affect adolescents’ smoking behavior [17,26,27]. Web-based interventions that deliver gender-sensitive, health-related information on the relationship between cigarette smoke and breast cancer thus appear to represent a promising means of reducing adolescent girls’ exposure to cigarette smoke.

Although Web-based interventions for adolescents have great potential, recent investigations of Web-based smoking cessation interventions for adolescents have not yet demonstrated substantial gains in efficacy [26,28-30]. However, interventions that aimed to prevent cigarette smoking initiation among nonsmokers have been more successful [17,31,32]. Given the limited success associated with Web-based smoking cessation interventions, it may be more productive to focus on the development of Web-based interventions that seek to prevent smoking initiation and to reduce SHS exposure among nonsmoking adolescent girls.

The aim of this study was to investigate the efficacy of targeted gender- and Aboriginal status-sensitive, breast cancer-specific, Web-based messages focused on the increased risk of breast cancer associated with cigarette smoke exposure. The outcomes included nonsmoking adolescent girls’ (1) knowledge of the causal link between cigarette smoke exposure and breast cancer, (2) perceptions of breast cancer risk associated with exposure to cigarette smoke, (3) smoking initiation, (4) intentions to

smoke in the future, and (5) stage of change related to avoidance of SHS at follow-up (6 months following the message delivery). We hypothesized that compared with a control group that received a standard message describing the carcinogenic effects of tobacco smoke, a greater proportion of girls exposed to the targeted, disease-specific intervention would identify exposure to cigarette smoke as a cause of, and risk factor for, breast cancer. We also hypothesized that compared with girls who received a standard message, a smaller proportion of girls who received the targeted, disease-specific intervention would try smoking, report intentions to try smoking in the future, and report doing nothing to avoid SHS exposure.

Methods

Overview

The study described in this article, entitled Supporting Tailored Approaches to Reducing Tobacco (START): Decreasing Breast Cancer Incidence, was a cluster randomized controlled trial nested within an ongoing Web-based prospective cohort study, the British Columbia Adolescent Substance Use Survey (BASUS). The BASUS study began enrolling students from 48 participating secondary schools in the fall of 2009 and surveyed participants every 6 months until the fall of 2012. All BASUS participants were 13 years of age or older, able to read and complete a Web-based survey in English, and provided informed consent, as well as written parental consent in schools where required. Although the majority of students completed their surveys online outside of school time, others completed the survey in school computer labs during scheduled class time. Students received reminders to complete each wave of the BASUS survey via school-based posters and announcements, as well as via personal email if requested by the participant. Students could retrieve their passwords via email using a lost password button on the BASUS website. All participants received a \$25 gift card as an honorarium for each wave of the survey completed, and the response rates for individual schools

ranged from 2% to 100%, with a 20% average. In the spring of 2011, schools were stratified into groups containing a similar number of study participants and randomly assigned to have their students receive either the targeted, breast cancer-specific intervention or the control message. The follow-up assessment was completed approximately 6 months later as part of the next wave of the BASUS study. For a complete description of the design of the randomized controlled trial and CONSORT statement, please refer to Richardson et al [33]. Ethical approval for both the BASUS and START studies was obtained from the University of British Columbia's Behavioural Research Ethics Board.

Intervention Condition

A tailored intervention message was designed to be sensitive to gender and Aboriginal status [33]. The resulting message included images of four different girls playfully holding bras, with the statement "Smoking affects more than your lungs" followed by "Cigarette smoke, even secondhand smoke, puts girls at risk for breast cancer at an early age." The message also included the following suggestions for action: "Avoid places where you and your friends are exposed to secondhand smoke. If you smoke, think about quitting. Do it for yourself and all the girls you know." An example of the intervention message is displayed in Figure 1. For girls self-identifying as Aboriginal, the same message was received at baseline, with the addition of a feather watermark (displayed in Figure 2), an important ceremonial symbol among people of First Nation or Aboriginal ancestry [33].

Following receipt of the intervention message at baseline, adolescent girls answered the following yes/no question: "Would you be interested in receiving information about the connection between cigarette smoke and breast cancer?" If a participant responded "Yes," she received additional information about the risk of cigarette smoke exposure and breast cancer upon completion of the survey (available on request).

Figure 1. Gender-targeted intervention message for girls. Source: Created by START study authors, who hold copyright to the image.

Smoking affects more than your lungs.

Cigarette smoke, even second hand smoke, puts girls at risk of **breast cancer** at an early age.

Avoid places where you and your friends are exposed to second hand smoke.

START decreasing breast cancer risk **UBC** a place of mind

If you smoke, think about quitting. Do it for yourself and for all the girls you know.

Figure 2. Gender- and Aboriginal status-sensitive, targeted intervention message for girls. Source: Created by START study authors, who hold copyright to the image.

Smoking affects more than your Lungs.

Cigarette smoke, even second hand smoke, puts girls at risk of **breast cancer** at an early age.

Avoid places where you and your friends are exposed to second hand smoke.

START decreasing breast cancer risk **UBC** a place of mind

If you smoke, think about quitting. Do it for yourself and for all the girls you know.

Control Condition

Students in the control group were presented with a standard message that cigarette smoke contains carcinogenic agents. The message was sourced from Health Canada's online library of health labels and warnings for cigarette tobacco [34]. This message included an image of an ash-laden burning cigarette standing against a black background (Figure 3), with the following statement:

Warning, you're not the only one smoking this cigarette. The smoke from a cigarette is not just

Figure 3. START control message. Source: Health Canada.



Participants

Participants included in the current analysis were nonsmoking adolescent girls, aged 13 to 15 years, who participated in the BASUS study. For baseline characteristics postrandomization, please refer to Richardson et al [33].

Measures

The baseline data collection for the current study occurred between April and June 2011; the follow-up data were collected between October and December 2011. The baseline survey questions determined the participants' demographic and SHS exposure characteristics, including age, ethnicity, family income (below average, average, or above average), and family history of breast cancer (yes or no). In addition, smoking behavior (ever tried smoking), intentions to smoke in the future, SHS exposure (parental smoking status, peer smoking status, cigarette smoke exposure at home, and extent of past month's exposure to SHS), and interest in receiving more information were assessed at baseline.

Approximately 6 months after the baseline dissemination of the intervention and control messages, the subsequent wave of the BASUS survey was administered. The following question was used to assess the girls' knowledge of the connection between cigarette smoke exposure and breast cancer: "Which of the following illnesses have been shown to be caused by exposure to cigarette smoke?", with the following response options: AIDS, arthritis, asthma, bladder cancer, breast cancer, common cold, diabetes, heart disease, lung cancer, measles,

inhaled by the smoker. It becomes secondhand smoke, which contains more than 50 cancer-causing agents

Following receipt of the standard message at baseline, adolescent girls answered the following yes/no question: "Would you be interested in receiving information about the connection between cigarette smoke and cancer?" If a participant responded "Yes," she received additional general information about the risk of cigarette smoke exposure and cancer upon completion of the survey questions (available on request).

schizophrenia, stomach cancer, or none of the above. Risk perceptions regarding cigarette smoke exposure and breast cancer were assessed by asking participants to respond to the following statement: "Being exposed to secondhand cigarette smoke increases my risk of getting breast cancer", with the following response options: strongly agree, agree, disagree, or strongly disagree. Intentions to smoke were measured with the following question: "Do you think you might try smoking cigarettes in the future?", with the following response options: probably yes, probably not, or definitely not. The following brief measure developed by our group was used to assess the girls' stages of change (ie, maintenance, action, preparation, contemplation, and precontemplation) related to avoidance of SHS: "When you are exposed to secondhand cigarette smoke, do you consistently do things to reduce your exposure to the smoke?", with the following response options: yes, I have been for more than 6 months; yes, I have been, but for less than 6 months; no, but I intend to in the next 30 days; no, but I intend to in the next 6 months; or no, and I do not intend to in the next 6 months [35].

Statistical Analysis

The primary aim of the analysis was to determine whether differences in the outcomes were associated with exposure to the intervention versus control messages. To account for possible confounding not controlled by random allocation, potential confounders were identified with bivariate tests—any variables found to differ ($P < .10$) between the treatment and control groups were included as covariates in subsequent multivariate models.

Bivariate analyses of the categorical data were conducted with Fisher's exact tests. Follow-up time (measured in months) was included in the multivariate models. A generalized estimating equation (GEE) was used for all multivariate regression models to adjust the standard errors of the parameter estimates for the correlated responses of students clustered within the same school [36]. Adjusted relative risks (ARRs) were estimated using a modified Poisson regression, with robust error variance [37] originally proposed by Lee and Chia [38] for binary outcomes [39]. The robust error variance estimator was used because Poisson regressions overestimate the standard errors of parameters arising from binary outcomes [37,40]. All statistical analyses were conducted with IBM SPSS Statistics Version 19.0. Although not part of the original aim, supplementary stratified analyses were performed to evaluate the impact of the intervention among the group of girls who requested more information about the relationship between cigarette smoke and (breast) cancer, and then among girls who did not request more information.

Results

Characteristics

A total of 745 nonsmoking adolescent girls completed the baseline survey, and 618 completed both the baseline and

follow-up surveys, providing a retention rate of 83.0%. Among the 127 girls lost to follow-up, 59 (46.5%) and 68 (53.5%) were in the control and intervention groups, respectively—results from a one-sample binomial test (hypothesized proportions of 50% in intervention and control groups) indicated that the difference in proportions lost to follow-up was not statistically significant ($P=.48$). Therefore, 618 nonsmoking girls from 74 schools (some students reported moving to a new school which increased the number of schools from 48 to 74), aged 13 to 15 years (mean age of 14 years), were included in the analyses. Of these girls, 242 received the intervention message and 376 received the standard control message. Among girls in the intervention group, 55 out of 242 (22.7%) requested more information about the relationship between cigarette smoke and breast cancer, and 64 girls out of 376 (17.0%) in the control group requested more information about the relationship between cigarette smoke and cancer—these proportions did not significantly differ ($P=.52$) by group. On average, 6 months elapsed between the baseline presentation of the messages and the follow-up assessment. Table 1 provides the participants' characteristics as well as the SHS exposure characteristics. Differences in age at follow-up, family income at baseline, family history of breast cancer at follow-up, and parental smoking status at follow-up were statistically significant ($P<.10$) between intervention and control groups.

Table 1. Personal and secondhand smoke exposure characteristics of nonsmoking adolescent girls by group allocation.

Characteristic	Control, n (%) (n=376)	Intervention, n (%) (n=242)	Total, n (%) (n=618)	P value ^a
Demographics				
Age in years (at follow-up)				
13	20/376 (5.3)	5/242 (2.1)	25/618 (4.0)	<.001
14	157/376 (41.8)	56/242 (23.1)	213/618 (34.5)	
15	199/376 (52.9)	181/242 (74.8)	380/618 (61.5)	
Ethnicity (at baseline)				
Aboriginal	27/372 (7.3)	22/237 (9.3)	49/605 (8.1)	.50
Non-Aboriginal	343/370 (92.7)	215/237 (90.7)	558/608 (91.8)	
Family income (at baseline)				
Below average	24/348 (6.9)	7/233 (3.0)	31/574 (5.4)	.04
Average	280/348 (80.5)	183/231 (79.2)	463/579 (80.0)	
Above average	44/349 (12.6)	41/231 (17.7)	85/578 (14.7)	
Responded "Yes" to "Family history of breast cancer" (at baseline)	66/357 (18.5)	64/236 (27.1)	130/591 (22.0)	.02
SHS exposure				
Responded "Yes" to "Parent(s) smoke(s)" (at follow-up)	101/338 (29.9)	40/223 (17.9)	141/562 (25.1)	.001
Responded "Yes" to "Friends smoke" (at follow-up)	57/295 (19.3)	27/191 (14.1)	84/488 (17.2)	.18
Answered "Yes" to "Does anyone smoke in your home every day or almost every day?" (at follow-up)	41/363 (11.3)	17/239 (7.1)	58/604 (9.6)	.12
Past month's exposure to SHS (at follow-up)				
Every day	16/372 (4.3)	5/238 (2.1)	21/600 (3.5)	.60
Almost every day	38/368 (10.1)	27/237 (11.4)	65/607 (10.7)	
At least once a week	103/369 (27.9)	68/236 (28.8)	171/604 (28.3)	
At least once in past month	166/369 (45.0)	111/236 (47.0)	227/495 (45.8)	
Never	46/368 (12.5)	25/236 (10.6)	71/607 (11.7)	
Other characteristics				
Intentions to try smoking in future (at baseline)				
Probably yes	16/363 (4.4)	5/238 (2.1)	24/585 (4.1)	.71
Probably not	73/361 (20.2)	47/238 (19.7)	102/586 (17.4)	
Definitely not	272/361 (75.3)	185/238 (77.7)	459/585 (78.5)	
Time elapsed to follow-up, months (SD)	5.82 (0.77)	5.84 (1.10)	5.83 (0.94)	.77 ^b

^aBased on Fischer's exact test.

^bBased on independent samples *t* test.

Knowledge and Risk Perceptions of Cigarette Smoke Exposure and Breast Cancer at Follow-Up

As shown in Table 2, after adjusting for differences in age, family income, family history of breast cancer, parental smoking status, and time elapsed to follow-up, the girls who received the intervention message were 33% more likely than girls that received the control message to identify breast cancer as an

illness caused by exposure to cigarette smoke (ARR 1.33, 95% CI 1.05-1.68).

After adjusting for differences in age, family income, family history of breast cancer, parental smoking status, and time elapsed to follow-up, the girls who received the intervention message were 10% more likely than girls in the control group to agree with the statement that being exposed to SHS increases

their risk of breast cancer (ARR 1.10, 95% CI 1.02-1.20) (see [Table 2](#)).

Table 2. Knowledge, risk perceptions, smoking behavior, intentions, and stage of change related to cigarette smoke exposure and breast cancer, by group allocation, at follow-up.

Follow-up assessment	Control, n (%) (n=376)	Intervention, n (%) (n=242)	Total, n (%) (n=618)	ARR ^a or unadjustedRR ^b (95% CI)
Knowledge and risk perceptions				
Responded “Yes” to “Breast cancer is caused by exposure to cigarette smoke.”	107/376 (28.5)	96/242 (39.7)	203/618 (32.8)	1.33 ^a (1.05-1.68)
Responded “Agree” to “Being exposed to secondhand cigarette smoke increases my risk of getting breast cancer.” ^c	252/314(80.3)	199/224 (88.8)	451/538 (83.8)	1.10 ^a (1.02-1.20)
Smoking behavior and intentions				
Responded “Yes” to “Tried smoking.” ^d	13/376 (3.5)	9/239 (3.8)	22/613 (3.6)	1.14 ^b (0.48-2.69)
Intentions to try smoking in the future				
Probably yes or probably not	75/354 (21.2)	51/231 (22.1)	126/585 (21.5)	1.00 ^a (0.98-1.03)
Definitely not	279/354 (78.8)	180/231 (77.9)	459/585 (78.5)	
Stage of change related to avoidance of SHS				
Answered “Yes” to “When you are exposed to secondhand cigarette smoke do you consistently do things to reduce your exposure to the smoke?” ^e	241/296 (81.4)	161/196 (82.1)	402/492 (81.7)	0.97 ^a (0.82-1.15)

^aAdjusted relative risk for differences in income, age, parental smoking status, family history of breast cancer, and time elapsed to follow-up.

^bUnadjusted relative risk (URR) for differences in income, age, parental smoking status, family history of breast cancer, and time elapsed to follow-up.

^c“Strongly agree” and “agree” were collapsed as “agree”, and “strongly disagree” and “disagree” were collapsed as “disagree”, which was the reference group.

^dEither tried cigarettes or roll-your-own cigarettes in the time between baseline and follow-up.

^eResponded either “Yes, for more than 6 months” or “Yes, but for less than 6 months.”

Smoking Behavior, Intentions to Smoke, and Stage of Change Related to Avoidance of SHS

As shown in [Table 2](#), no statistically significant treatment effects were observed for a change in smoking status (ie, having tried cigarette smoking between baseline and follow-up), intentions to try smoking, or stage of change related to avoidance of SHS.

Stratified Analyses to Investigate Impact of Intervention Within Groups Defined by Requesting More Information

After stratifying groups by whether or not the girls requested more information about the relationship between cigarette smoke and (breast) cancer, we examined all outcomes analyzed in the prior multivariate models (knowledge and risk perceptions, smoking behavior and intentions, and stage of change related to avoidance of SHS) using univariate analyses (Pearson Chi-square tests). Among girls who requested more information (n=119), a significantly greater proportion of girls in the intervention group (27/48, 56%) compared with the control group (14/71, 20%) identified breast cancer as an illness caused by exposure to cigarette smoke ($P=.003$). Among girls who did not request more information (n=499), a significantly greater proportion of girls in the intervention group (170/194, 87.6%)

compared with the control group (244/305, 80.0%) agreed with the statement that being exposed to SHS increases their risk of breast cancer ($P=.03$). All other outcomes of interest did not significantly differ in these stratified analyses.

Discussion

Principal Findings

The objectives of this study were to evaluate the effects of a targeted gender- and Aboriginal status-sensitive, breast cancer-specific, Web-based message on nonsmoking adolescent girls’ (1) knowledge of the causal link between cigarette smoke exposure and breast cancer, (2) perceptions of breast cancer risk associated with exposure to cigarette smoke, (3) smoking initiation, (4) intentions to smoke, and (5) stage of change related to avoidance of SHS at follow-up (ie, 6 months after the message delivery). The results indicate that the intervention message had positive effects on awareness of cigarette smoke exposure as a causal agent of, and risk factor for, breast cancer among nonsmoking girls approximately 6 months following message dissemination. Compared with the girls who received the standard control message, the girls who received the intervention message were 33% more likely to identify breast

cancer as an illness caused by exposure to cigarette smoke and 10% more likely to agree with the statement that being exposed to SHS increases their risk of breast cancer. Furthermore, a similar pattern of results was found in groups stratified by whether or not the girls requested more information about the relationship between cigarette smoke and (breast) cancer.

This is the first intervention we are aware of specifically designed to evaluate the effect of a brief Web-based intervention on awareness of the relationship between SHS and breast cancer. Furthermore, this study considered both changes in perceived risk regarding the link between exposure to SHS and breast cancer, as well as smoking intentions and behavior at follow-up. Two teams of researchers have tested online interventions to reduce cigarette use and intentions to smoke among adolescents [26,28]. They both reported reduced odds of future smoking intentions, and the analyses by Norman et al revealed reduced odds of cigarette use by the nonsmokers in the intervention arm. However, these studies utilized multicomponent interventions. Norman et al implemented a 5-phase, interactive program in Smoking Zine [26], which included a virtual point-of-sale that evaluated the cost of smoking, followed by smoking use assessments and a pros versus cons evaluation of smoking and being smoke free. Buller et al evaluated Consider This, a comprehensive 6-module program based on Bandura's Social Cognitive Theory, which included assessments of perceived social norms concerning the prevalence of smoking, future smoking expectations, and smoking prevalence among adolescents (resistance efficacy) [28]. In comparison, our intervention was brief, which may explain why we found significant gains in knowledge, but no change in actual behavior.

Findings from our study, which indicate that brief, targeted, breast cancer-specific messages can raise girls' awareness of the link between breast cancer and cigarette smoke exposure, add to the small but growing body of literature about the benefits of using the Internet to deliver messages to raise awareness and ultimately effect health behavior change. For example, in a recent study 25% of 497 adolescents reported changing their behavior (eg, nutrition and/or physical activity) based on findings in online searches for health information [24]. Indeed, several trials have demonstrated that Web-based health promotion interventions can be targeted and widely disseminated in an effective and relatively inexpensive manner [41,42]. In addition, there may be the possibility of using existing online commercial marketing services to disseminate targeted messages on a large scale at very low cost. Although the results of this study indicate that the START messages would likely increase

awareness of the risk of breast cancer associated with cigarette smoke exposure, further research is needed to determine how changes in awareness or perceived risk could be leveraged to include subsequent reductions in smoking initiation and SHS exposure.

Limitations

This study is not without limitations. The purpose was to compare a generic control message with targeted gender- and Aboriginal status-sensitive, breast cancer-specific (intervention) messages. Given that the control message did not contain breast cancer-specific information it is not possible to disentangle the influence of the breast cancer-specific information from the other aspects of the gender tailoring of the intervention message. The positive outcomes of the intervention were increases in girls' knowledge and risk perceptions related to cigarette smoke exposure and breast cancer, not with actual behavior change (eg, reduced smoking initiation or stage of change related to avoidance of SHS). However, the latter, nonsignificant findings could have resulted from the small number (22/613) of girls who reported having tried smoking at the time of follow-up. Future studies could address this limitation by employing a much larger sample. These studies could add to the results of the current investigation by examining behavioral change among an oversampling of girls' who have already tried smoking. Additionally, if a second no-information control group had been included as a reference (ie, one that did not receive any message), larger intervention effects may have been found. The generalizability of these findings is limited—they may not be relevant to other age groups and ethnicities.

Conclusions

The study findings suggest that a brief, targeted, disease-specific and gender-sensitive, Web-based message influenced girls' knowledge of cigarette smoke exposure as a risk factor for, and causal agent of, breast cancer, thereby supporting the use of this type of intervention in future trials. Brief informational interventions delivered via the Internet appear to be effective, far-reaching forms of health promotion that have the potential for long-term effects on adolescents' knowledge and risk perceptions with regard to cigarette exposure and breast cancer. Future investigations of Web-based interventions could employ repeated exposure of the targeted message, or they could implement a multistep design and incorporate short message service (SMS) text messaging or interactive voice responses to understand how to increase the effectiveness of these types of interventions.

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Conflicts of Interest

None declared.

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Abbreviations

- ARR:** adjusted relative risk
 - BASUS:** British Columbia Adolescent Substance Use Survey
 - GEE:** generalized estimating equation
 - SHS:** secondhand smoke
 - SMS:** short message service
 - START:** Supporting Tailored Approaches to Reducing Tobacco
 - URR:** unadjusted relative risk
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Protocol

Community-Based Rehabilitation Post Hospital Discharge Interventions for Older Adults With Cognitive Impairment Following a Hip Fracture: A Systematic Review Protocol

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Abstract

Background: Hip fractures among older adults remain a public concern. Consequences of a hip fracture include the subsequent decline in function and mobility for the older adult, and an increased burden placed upon their caregivers and the health care system. The consequences may be more challenging if an older adult also has a compromised cognitive reserve. Although rehabilitation programs have proven effective, the best practices and resources required to maintain the gains in function and mobility, to negate diminution of effect, and to enable this patient population to continue living at home are currently unknown.

Objective: The objective of this study is to develop a systematic review protocol focused on identifying the evidence and evaluating the effectiveness of post discharge rehabilitation programs for older adults with a cognitive impairment following a hip fracture.

Methods: The search strategy will include a combination of text words and subject headings relating to the concepts of cognitive impairment, dementia, delirium, cognitive reserve, and hip fractures. Searching various databases will identify peer-reviewed journal articles. There will be two independent reviewers who will screen the titles and abstracts to determine which articles comprise a rehabilitation intervention within a community setting prior to being included for a full article review. A data extraction form and an evidence and quality checklist will be used during the full article data analysis and synthesis. It is expected that there will be a paucity of studies that focus on post discharge rehabilitation interventions for older adults with cognitive impairment following a hip fracture, and few studies that use the same or similar outcome measures. However, if possible, a meta-analysis will be conducted on studies that used similar outcome methods.

Results: This review will synthesize knowledge focusing on activities to maintain and restore function in older adult patients with cognitive impairment once they have completed their active rehabilitation program and return home. A synthesis of the findings will be conducted to determine which components of the interventions identified were the most advantageous to the patient population. The results will be used to develop a multi-faceted post discharge rehabilitation intervention aimed at enabling older adults to return and remain living at home after a hip fracture.

Conclusions: The aim of this systematic review is to generate results that can be used to create interventions that focus on the care necessary to enable older adults to remain living at home post discharge from acute or inpatient rehabilitation care for a hip fracture. With the support and contributions by our associated knowledge users, this systematic review will be used to help inform procedures and policies to facilitate the necessary care and resources required by our patient population.

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KEYWORDS

hip fracture; rehabilitation; cognitive impairment; community; at-home; intervention

Introduction

Older Adults and Hip Fractures

With approximately 35,000 a year in Canada and projections that indicate that the incidence will increase nearly four-fold by 2041, hip fractures remain a public health concern [1,2]. As a consequence, a hip fracture is often a catastrophic event that results in significant impairment in mobility, independence, and ability to live in the community [2]. The event of a hip fracture and the recovery period afterwards is complicated further by the presence of a cognitive impairment. Health care services are currently fragmented and limited, such that few patients with a cognitive impairment (CI), such as dementia or delirium, are able to access rehabilitation services [3-5]. Although there is evidence to suggest that community-based rehabilitation programs can be beneficial [6,7], there has yet to be a synthesis of studies that focused on community-based rehabilitation interventions post discharge from the hospital for older adults with a CI following a hip fracture.

In response to the need for better services for older adults with CI, previous research involved the development of a Patient-Care Rehabilitation Model for patients with a hip fracture including persons with CI (PCRM-CI) [8]. Outcomes at discharge revealed that patients in the PCRM-CI group were more likely to return home post discharge (vs being admitted to long-term care), despite having an average age above 80 years and multiple comorbidities. Longitudinal data showed that at 3 months post discharge mobility scores among persons with CI deteriorated significantly, but recovered to discharge levels at 6 months, thus, suggesting that the initial decline in mobility status may be mitigated if additional services are provided post discharge [8]. Nonetheless, if the progress made during inpatient rehabilitation is negated by discharging the patient home without proper resources or continued rehabilitation, then the health of the patient will be impacted, and the burden on caregivers and the health care system will be onerous. The next important step is developing interventions to reduce decline once the older person with CI is discharged home. A recent systematic review on early discharge planning and long-term outcomes for older adults, with and without CI post hip fracture, identified a gap in the knowledge of post discharge rehabilitation requirements that are necessary to achieve these recovery outcomes [9]. Thus, the review protocol presented in this paper will concentrate on community-based rehabilitation, post hospital discharge interventions, focused on older adults with CI following a hip fracture.

Community-Based Rehabilitation Post Discharge Studies

Studies examining community-based rehabilitation post discharge from the hospital have found promising results. Binder et al [6] conducted a randomized controlled trial to determine if extended outpatient rehabilitation improved the physical function and reduced disability among older adults following a hip fracture. They compared progressive resistance training to low-intensity home-based exercise, and provided evidence in support of extended outpatient rehabilitation to improve physical performance, mobility, and quality of life, and reduce disability among community-dwelling older adults following a hip fracture. Home-based exercise programs can also result in an improved activity level compared to those who received usual care [6]. Orwig et al [7] defined usual care as the standard 2 to 4 weeks of inpatient rehabilitation, while home-based rehabilitation was described as a combination of aerobic activities, strength training, and self-efficacy based motivation [7]. Although the study demonstrated the feasibility of providing a home-based rehabilitation program, the study involved only women, primarily focused on exercise, and included only participants who were cognitively intact [7]. Shyu et al [10] implemented an interdisciplinary intervention that consisted of geriatric consultation, continuous rehabilitation, and discharge planning for Taiwanese older adults with CI following hospital discharge for a hip fracture [10]. In their 2 year follow-up study, it was found that the intervention improved the postoperative cognitive functioning [10]. Thus, there is some evidence to support that post discharge rehabilitation programs can have a positive impact on both the physical and cognitive functioning of older adults with CI following a hip fracture.

There have been several systematic reviews of interventions implemented to aid older adults with a musculoskeletal deficiency, such as hip fractures [11-19]. There are limitations, however, to these prior systematic reviews. In one review, Auais et al [19] found evidence indicating that extended exercise rehabilitation programs can have a significant impact on the functional abilities of individuals with hip fractures [19]. It was also determined that the community-based programs had larger effect sizes than home-based programs [19]. Mehta and Roy [16] made a comparison between rehabilitation outcomes from multiple modes of delivery (ie, home-based physiotherapy vs inpatient, outpatient, and no treatment) for patients following a hip fracture [16]. The results were inconclusive for indicating a mode of delivery with greater benefits to patients [16]. Stolee et al [17] compared the outcome of home-based versus inpatient rehabilitation interventions for older adults with musculoskeletal conditions [17]. The results suggested that the outcomes

achieved by home-based rehabilitation programs were favorable in a number of studies [17].

There are pervasive limitations among prior systematic reviews. First, the results were not specific to patients with hip fractures, but covered a broad spectrum of musculoskeletal conditions [17]. Second, several reviews included only individuals who were cognitively intact [15,17,19]. Third, others examined only one rehabilitation modality (ie, exercise or physiotherapy) or one outcome variable [16,19]. Fourth, some studies only focused on inpatient interventions [11,18]. The systematic review protocol presented in this paper will look at the evidence for post discharge rehabilitation interventions in multiple modes in community settings, including home-based, for older adults with CI following a hip fracture. This systematic review will include studies that followed patients discharged from acute care and inpatient rehabilitation settings. *Rehabilitation* can encompass a vast number of activities, and can be broadly defined as health care activities that aim to improve patient well being and reduce caregiver burden [20]. Such activities may include, but are not limited to, exercise programs, strengthening, fall prevention, and home environment assessment and modifications. We are defining *community-based rehabilitation post discharge* as interventions initiated once an individual is discharged home after an acute phase of an illness is stabilized, and may include: (1) a physical component (eg, exercise, physiotherapy), (2) a cognitive component (eg, cueing, memory enhancing games), (3) a social activity or social engagement component, and (4) a pain management component. Post discharge rehabilitation takes place in the community in multiple settings, such as outpatient clinics or in the home of the individual. Key outcomes may include, function, mobility, quality of life, return to normal living, mortality rates, and engagement in the community. Thus, this review will examine a comprehensive range of outcomes including function, mobility, return to normal living, and activities of daily living, which has not previously been captured. The aim of this study is to systematically examine the literature for evidence that informs the design and implementation of the best discharge rehabilitation care pathway for older adults with CI following a hip fracture.

Methods

The Systematic Review

Following discharge from the hospital (ie, acute care or inpatient rehabilitation), the best care pathway will include interventions that: (1) maintain or continue to improve function, mobility, quality of life, and return to normal living; (2) prevent readmissions to the hospital or admissions to long-term care homes; and (3) reduce caregiver burden, health care costs, and mortality. This systematic review will look at the evidence for all modes of post discharge rehabilitation interventions in community settings, including home-based, for older adults with a CI following a hip fracture. Meta-analysis will be performed where possible. This systematic review will follow the methods described in the Cochrane Handbook for Systematic Reviews of Intervention, and be reported in compliance with

the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [21].

Data Sources and Search Methods

A comprehensive literature search will be conducted to identify any eligible studies. The search strategy will include a combination of text words and subject headings relating to the concepts of CI, dementia, delirium, cognitive reserve, and hip fractures (see [Multimedia Appendix 1](#) for more information). Searching Medline, Medline In-Process, Pubmed, PsycINFO, Embase, CINAHL, A*MED, Ageline, The Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effect, and the Allied Health Evidence databases will identify peer-reviewed journal articles. An information specialist (JB) will conduct the database searches. Additionally, the search will include contacting the authors of included papers to request additional published or unpublished work, requesting unpublished work from experts in the field, and scanning conference abstracts and references from included studies.

Article Screening and Selection

There will be two reviewers (CC, PMvW) that will independently screen the titles and abstracts of the articles. During the screening stage, the reviewers will determine whether the articles include: (1) a rehabilitation intervention, and (2) in the community interventions. The reviewers will use a screening form developed by the research team to guide them through the decision process for full-text screening.

A challenge that may arise is disagreement between independent reviewers when screening titles, abstracts, and full articles. In the case of a disagreement arising, all team members will be provided with the relevant material to come to a consensus decision. Research team meetings will be held on a regular basis to discuss articles, to ensure consensus in decisions, and to discuss any complications and findings.

Inclusion Criteria

Publications that report the following will be considered for inclusion: (1) an intervention aimed at maintaining or improving function; (2) participants who are 65 years of age and older; (3) participants with CI; and (4) participants who suffered a hip fracture. Publication types to be included are randomized controlled trials, prospective (longitudinal), retrospective (longitudinal), cross-sectional, cohort, and quasi-experimental studies. According to the Cochrane Collaboration, a meta-analysis typically excludes nonrandomized controlled trials because of the higher risk of bias. However, we have chosen to include nonrandomized studies in order to collect a comprehensive overview of the evidence. To address concerns of bias, prior to the conduct of the meta-analysis, we will verify the risk of bias in each study, and based on these assessments, decide on the meta-analysis. The search will be limited to English and French articles. Each database will be searched for its entire scope of content, since the inception of the databases to the current date.

Exclusion Criteria

Publications will be excluded if: (1) there is no community component to the rehabilitation program or intervention; (2) the study population includes patients with stroke, Parkinson's, or frontal-temporal dementia, as these diseases have different physiological and behavioral markers; and (3) there is insufficient information in the publication to extract the necessary data (ie, editorials, expert opinions, qualitative studies, review articles, and publications that only include an abstract). Note; if there is insufficient information in the publication, where applicable, the authors will be contacted to retrieve additional information.

Data Abstraction

For each of the included studies, the reviewers will independently extract data based on the developed extraction form. This includes information about the: (1) study (eg, aim of the study, sampling method, source of data, recruitment period, intervention duration, and study duration), (2) participants descriptors (eg, sample size, age, sex, type of hip fracture, type of CI, prefracture living location, and discharge location), (3) interventions (eg, components, setting, assessments, and scales used), (4) outcomes, (5) statistical analyses, and (6) randomization, allocation, and blinding methods.

Data Analysis and Synthesis

It is expected that there will be a paucity of studies that focus on post discharge rehabilitation interventions for older adults with CI following a hip fracture, and few studies that use the same or similar outcome measures. If it is possible to conduct a meta-analysis of those studies which used similar outcome methods, the analysis of data will involve calculating a pooled effect size, calculating confidence intervals, testing for homogeneity, and determining publication bias following the methods as described by the Cochrane Collaboration using Review Manager software [22]. If it is determined that the outcome data is continuous in nature, a difference between means will be calculated.

Statistical heterogeneity will be determined using the *i*-squared and chi-square statistical tests [22]. If the *i*-squared value is equal to or less than 40 percent, a meta-analysis will be performed [22]. All statistically significant analyses will be interpreted using a cut-off *P* value of 5%. Funnel plots will be constructed to determine publication bias. Effect size will be on the x-axis, and sample size will be on the y-axis. Publication bias will be assumed minimal if the plot resembles a funnel with the base down.

As it is possible that the interventions may be implemented at different times or that assessments may be taken at different times, the included studies will be grouped into one of two categories. The first group will be categorized as "short-term", in which the intervention or assessments take place within the first six months post discharge. If the intervention or assessments take place six months or later after the time of discharge, these studies will be categorized as "long-term". If deemed appropriate, pooled estimates will then be created for both short-term and long-term studies for each outcome. To assess

the impact of combining the data into these two groups, sensitivity analyses will be used.

CI may be defined within the studies as mild, moderate, or severe. Thus, a sub analysis will be conducted to determine if outcomes are more favorable among participants with less CI and vice versa. A sensitivity analysis will be performed by recalculating the meta-analysis to specifically make comparisons at each of the three levels of CI.

Critical Appraisal Techniques

To evaluate the evidence and quality levels of the publications used in this review, we will use the Downs and Black checklist [23]. Many intervention studies in health care are not conducted as randomized controlled trials (RCTs); thus, it is imperative that we select a methodological quality assessment tool that can assess both RCTs and non-RCTs. The Downs and Black checklist was developed to assess both RCTs and non-RCTs, and has been previously used in a systematic review examining hip fracture rehabilitation practices of older adults [13,23]. The reviewers of the articles will also independently score the quality of the included studies, and any disagreements will be discussed and resolved by the research team.

Results

This study aims to determine what, if any, rehabilitation interventions are provided to older adults with a CI who have experienced a hip fracture after they have been discharged from acute care or in-patient rehabilitation. Currently, a synthesis of the findings is being conducted to determine which components of the interventions identified were the most advantageous to the patient population. The projected completion date for the study is the end of 2014. The results will be used to develop a multi-faceted post discharge rehabilitation intervention aimed at enabling older adults to return and remain living at home after a hip fracture. Once the results of this review are known, the research team will organize an international symposium in Canada to present the findings to knowledge users and policy makers. We will invite influential individuals in the field to attend, including: (1) researchers, (2) policy makers, and (3) relevant networks and organizations, and health care professionals. The symposium will use the results of the review and the influence of the panel of decision-makers and experts to develop new guidelines for providing care for older adults with CI following a hip fracture to remain living at home safely.

Discussion

Creating Interventions for Older Adults With Hip Fractures and Cognitive Impairment Post Discharge

For an older adult with a hip fracture, the subsequent decline in function and mobility can be debilitating, resulting in a great burden placed on their caregivers and the health care system. Thus, this review will synthesize knowledge focusing on activities to maintain and restore function in older adult patients with CI once they have completed their active rehabilitation program and return home. Our team of experts, including health care providers, rehabilitation practitioners, and researchers, has already been making great strides toward improving inpatient

rehabilitation services received by older adults, especially those with CI [8]. The aim of this systematic review is to generate results that can be used to create interventions that focus on the care necessary to enable older adults to remain living at home post discharge from acute or inpatient rehabilitation care for a hip fracture. With the support and contributions by our associated knowledge users (physicians, policy makers, and family members of the patient population) this systematic review will be used to help inform procedures and policies to facilitate the necessary care and resources required by our patient population.

Ultimately, we expect our findings to benefit end users in countries around the world.

Conclusions

The best practices and resources required to maintain the gains in function and mobility, to negate diminution of effect, and to enable this patient population to continue living at home are currently unknown. With the current initiative in Ontario focused on affording older adults the ability to “age in place” [24], it is imperative to understand the evidence that exists in the literature to enable older adults post discharge from hip fracture rehabilitation to remain living in their homes. Thus, the overall aim of this review will be to identify the evidence and evaluate the effectiveness of post discharge rehabilitation programs.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy example for Medline Database: Ovid MEDLINE 1946 to January Week 2 2014.

[[PDF File \(Adobe PDF File\), 33KB - resprot_v3i3e47_app1.pdf](#)]

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Abbreviations

CI: cognitive impairment

PCRM-CI: Patient-Care Rehabilitation Model of patients with a hip fracture including persons with CI

RCT: randomized controlled trial

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Protocol

Clinical Utility of an Observation and Response Chart With Human Factors Design Characteristics and a Track and Trigger System: Study Protocol for a Two-Phase Multisite Multiple-Methods Design

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Abstract

Background: Clinical deterioration of adult patients in acute medical-surgical wards continues to occur, despite a range of systems and processes designed to minimize this risk. In Australia, a standardized template for adult observation charts using human factors design principles and decision-support characteristics was developed to improve the detection of and response to abnormal vital signs.

Objective: To describe the study protocol for the clinical testing of these observation and response charts (ORCs).

Methods: We propose a two-phase multisite multiple-methods design to test the initial clinical utility of the charts in 10 hospitals of differing types and sizes across state jurisdictions in Australia. Data collection in the first phase includes user surveys, observations and field notes by project officers, handover de-briefs (short interviews with small groups of staff), and an audit of ORC documentation completion compared to the site's existing observation chart. For the second phase, data will be collected using a retrospective audit of observation documentation from the previous hospital observation chart, prospective audit of observation documentation following implementation of the selected ORC, user focus groups, observational field notes, and patient outcome data from routinely collected organizational data sources.

Results: Site selection and preparation, project officer training, chart selection and implementation, participant recruitment, and data collection has been completed and the analysis of these results are in progress.

Conclusions: This detailed description of these study methods and data collection approaches will enable a comprehensive assessment of the clinical utility of these newly developed track and trigger charts and will be useful for clinicians and researchers when planning and implementing similar studies. Potential methodological limitations are also noted.

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KEYWORDS

patient deterioration; track and trigger; rapid response system; observation charts; human factors design

Introduction

Widespread deficiencies in detecting and responding to clinical deterioration in adult patients in general wards at acute care hospitals continue despite a range of practice initiatives [1]. One key strategy to reduce serious adverse events has been the evolution from “cardiac arrest” teams to medical emergency teams (METs): in-hospital mortality rates now approximate 80% for cardiac arrests, 25% for MET calls, and 15% for patients with abnormal vital signs [2]. However, practices around the “afferent limb” of the rapid response system (RRS) (ie, patient monitoring, risk assessment, and event detection) remain identified areas for improvement [1]. At the core of these practices are patient observation charts.

Paper-based observation charts remain the dominant approach for documenting clinical observations of adult patients in acute general wards of Australian hospitals. With the continued identified failure to recognize and respond to signs of clinical deterioration evident [3], development and evaluation of charts have become a focus of recent work in Australia [4,5] and internationally [6-9].

The Australian Commission on Safety and Quality in Health Care (ACSQHC) implemented a program of work on “Recognizing and Responding to Clinical Deterioration” [10], focusing on ensuring that adult acute care medical-surgical patients whose clinical condition deteriorates receive appropriate and timely care and treatment. One initiative was to develop an evidence-based adult general observation chart that incorporated a system for recording patient observations, supporting accurate and timely recognition of clinical deterioration, and specifying prompt actions when deterioration was observed. Using human factors principles [11], the chart was designed to record physiological parameters (Element 1.6 of the National Consensus Statement; Respiratory Rate, Oxygen saturation, Heart Rate, Blood Pressure, Temperature, Consciousness Level), display thresholds for each physiological parameter or combination of parameters that indicate abnormality, specify the physiological parameters and other factors that trigger escalation of care, and include actions required when care is escalated [12].

The resulting adult deterioration detection system (ADDS) charts were designed with a multiparameter early warning scoring system (EWSS) using heuristic analysis [11] and were tested in a simulated environment [11,13-15]. The EWSS assigned scores from 0-5 for specified clinical parameters (described below), according to the level of derangement from normal, and then summed to produce a total score. A second version of the ADDS chart also included a separate table on the chart for scoring systolic blood pressure [16].

Three additional observation and response charts (ORCs) were subsequently developed by the ACSQHC after simulation testing to account for different track and trigger systems (TTS) across the full range of health services in Australia [12]. Each version used multiparameter vital signs alerts for clinical deterioration, and with one (Emergency Call), two (+ Clinical Review), or four levels (+ Senior Nurse Review, Increased Clinical Surveillance) of available clinical response. These additional

charts were not tested in a simulated environment prior to the proposed clinical testing reported here.

Each version of the ORC is structured as a double-sided A3-sized form with a layout of a left binding margin and an off-center fold from the right. When folded, the cover page highlights to the user any other observation charts in use and modifications to parameter values for this patient. When folded out to the right, the inside left page contains the charting area for documentation of observations for nine specified parameters (in order from the top of the form: respiratory rate, oxygen saturation, oxygen flow rate, blood pressure, heart [pulse] rate, temperature, consciousness, hourly/4-hourly urine output, and pain score). All chart versions use the same graphing section [12]. Importance, not frequency, guided the location of each section in the chart. This charting area provided 18 columns for documenting observations. Every third column had a bold line to reduce “column-shift” error [17]. Each of the parameters had a range of normal values (with no shading) and a series of abnormal ranges with different colored shading, depending on the number of escalation response levels at each site. See [Figure 1](#) for an example of a four-response level chart [12].

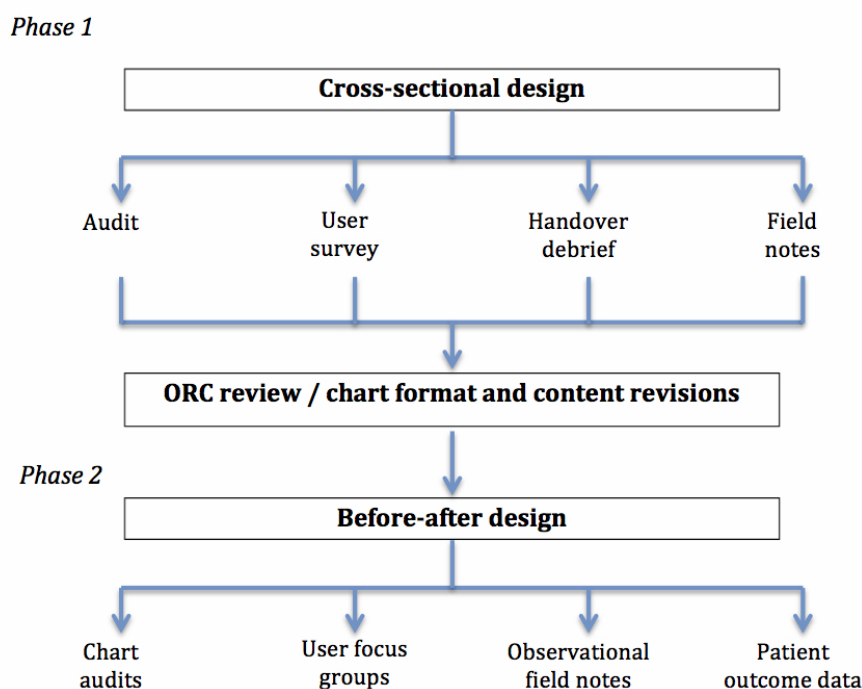
When graphing observations, users are instructed to place a dot (•) in the center of the box, which included the current observation in its range of values, and connect it to the previous dot with a straight line. For blood pressure, the “v” and “^” symbols are used for systolic and diastolic values respectively, and connected by a vertical dotted line. Pain score is the only parameter to use written numeric values, from 0 (none) to 10 (worst). When an observation is recorded in a shaded area, recommended actions are noted on the chart to guide clinicians to initiate an appropriate response, unless a modification has been documented previously on the ORC [12]. Use of colored bands was developed to delineate vital sign abnormalities, initiate a change in clinician behavior, and increase RRS triggering reliability using site-specific predefined actions [1].

The inside right page provides information only for the user, including the response criteria and actions required (it is not for writing information on). The final page contains sections to record interventions associated with abnormal vital signs, clinical review requests, and additional observations [12].

The aims and scope of our project are outlined in a competitive tender process from the ACSQHC. The first study aim is to test initial usability (ease of use) and clinical utility of the ORCs in general adult medical/surgical wards. The related objectives for this first phase are to examine whether the ORCs (1) are suitable for observations of adult medical-surgical patients and prompt a response for episodes of clinical deterioration, (2) have any sections that require modifications, and (3) could be introduced and applied in practice with minimal training.

Five versions of the charts [12] are available for testing in the clinical sites: (1) ADDS+: using an EWSS with a table for scoring systolic blood pressure, and four TTS (response) levels (Increased Clinical Surveillance, Senior Nurse Review, Clinical Review, Emergency Call), (2) ADDS-: using an EWSS without scoring systolic blood pressure, and four response levels (as above), (3) ORC R4: using a multiparameter TTS with four response levels (as above), (4) ORC R2: using a multiparameter

Figure 2. Study design.



Site Selection and Sample

Expressions of interest will be sought from hospitals across all state jurisdictions using the ACSQHC contacts list. In the response, interested sites will confirm their ability to support implementation and evaluation of the ORC in their facility. Ten clinical sites will be selected in consultation with the ACSQHC. A sample will be selected that reflects differences in hospital size and level of service, preferred chart template, and location.

An executive from selected sites will be invited to engage as a champion for the project, liaising with key stakeholders, supporting the site-based project officer, and profiling the work with all relevant clinical staff. Site-based project officers will be seconded for the project and supported by training workshops, project manager site visits, teleconferences, telephone, and email assistance.

Selection of Observation and Response Chart Version and Chart Modifications

Each site will select one of the five versions of the ORC that best matches their local escalation protocol and existing RRS for managing deteriorating patients. Each selected ORC template will then be modified to align parameter values with each site's rapid response team calling criteria and RRS protocol and practices.

Clinical Site Preparation

A site information package will be developed and distributed to each of the site executives and project officers and will also form part of the ethics application for each site (discussed below). The document will provide details of the different stages in this phase, as well as guidelines and tools for data collection, and different resources for the site-based project officer. A

training workshop is planned to be conducted centrally for all project officers. A full-day event will provide project orientation, including the context of patient deterioration and the ACSQHC's program of work, exploration of the ORC designs based on human factors development, introduction to the ORC Project and project team, and description of the data collection approaches using short demonstration videos, patient scenarios, and practice sessions.

Although training on completion of the chart for clinical staff is to be minimal as per the intent of the ACSQHC, staff preparation for data collection will be essential, and so each project officer will inform all relevant clinical staff (primarily nursing staff) about the new chart and the project. This is planned to include orientation to the design characteristics and components of the chart and the aims of the project and related data collection processes, specifically the need for dual-documentation of observations during the 24-hour data collection period. Given the issue of shift work and access to staff, this information will be provided in both written (information posters, information sheets in the communications folder or equivalent, email) and verbal forms (shift handovers preceding the data collection period, depending on staff roster patterns and practices).

For the required double documentation of patient observations, clinical staff will be requested to document on the hospital's current observation chart first as per usual practice, as this forms part of a patient's medico-legal record. They will then document the observations on the trial ORC during the same documentation activity, to minimize any variations between the two charts. On the designated data collection day for that ward, the project officer will distribute the selected chart for

commencement at the start of the observation day (planned to be early afternoon).

Data Collection Approaches

Phase 1

Summary

The multiple-methods approach for this initial phase will comprise an audit of the ORC for completeness of documentation of observations, compared to the hospital's existing observation chart, a self-report survey by users, handover debriefs (short interviews with small groups of clinical staff), and observations and field notes from the site-based project officer.

Any addition to workload of clinical staff is a risk to study compliance and feasibility, and therefore data collection is planned to minimize respondent burden by scheduling each ward to complete the dual-documenting of observations on the existing hospital chart and the designated ORC only within one 24-hour period. A continuous 24-hour cycle of observations in each ward is most appropriate for testing the clinical utility of the charts, including assessment on the use of charts at night, when ambient lighting is lower. A staged process will be developed for each hospital site, so that data collection for each ward can be undertaken in sequential 24-hour periods, separated by a data collation day to allow completion of data collection from the previous ward and preparation for the next ward.

Audits

Dual documentation will be a requirement during this phase as the ORC will not be an approved medical record at this stage, and the current hospital chart will therefore remain in practice as part of the legal medical record during the trial. Following completion of the 24-hour period of dual-documentation data collection for each ward, each project officer will audit the ORCs for completeness of documentation of observations, compared to the hospital's existing observation chart. These data will be entered via SurveyMonkey with guidelines provided to support the project officer. Compliance between the dual sets of documented observations will also be audited, comparing sets of vital signs on the ORC with sets of vital signs on the existing hospital chart to identify when (time of day) and where (variable on ORC) errors may occur. Any vital sign sets on the ORC that do not match the vital sign sets on the existing hospital chart will be considered as mismatched. Details of mismatched vital sign sets will be collected for a maximum of five sets per chart.

User Survey

A user-satisfaction survey will be completed by clinical staff at the end of their observation activities for the shift. The survey comprises 28 items relating to the design and components of the charts [15]. For ADDS charts, seven additional items relating to scoring and the blood pressure table will be included. Items will examine usability of the ORCs in the clinical setting, including clarity of text (size, font type), layout (size of chart, flow, and format of observation parameters), comprehensiveness, ease of documenting, and capacity to trigger a response for a deteriorating patient. Items are formatted as

dichotomous and Likert-scale response levels for ease of completion. Demographic characteristics of each user will also be collected, including designation and qualifications of staff, employment type, and employment experience. Staff designation, particularly in relation to nursing or other care staff, is important to collect, given that the intent of the ORC is for it to be used by all levels of clinical staff undertaking patient observations without specific training.

Both paper-based and online versions of the survey will be developed, with each taking approximately 5 minutes to complete. Each project officer will distribute the paper-based surveys to users at the beginning of their shift and then collect the surveys at the time of user completion, to ensure an optimal return rate and completeness of the survey. For staff that prefer and have access to Internet-enabled computers in their work area, a site-unique link to SurveyMonkey will be provided. Only one user survey per participant will be completed.

Handover Debrief

At the completion of each shift (particularly after night duty), the project officer will conduct short interviews with a group of staff. These debrief sessions will be audio-taped with participant permission, for project officers to group or theme staff views and experiences. The aim of these interviews is to identify and explore the broad issues for clinical staff related to documentation in the ORC. Guidelines will be provided to support the project officer.

Field Notes

Each site-based project officer will document field notes while observing practices relating to the use of the selected chart. During peak periods of observation (eg, 1000, 1400, 1800 hours), the project officer will observe staff observation practices and communicate briefly with users for any anecdotal comments on the clinical utility of the charts.

Chart Modifications Following Phase 1

Following Phase 1 analyses and discussion with the chart developers, applicable modifications to the ORCs will be implemented prior to Phase 2. Any information and training issues for Phase 2 will be addressed by a range of information resources such as a project plan, posters, materials for use during in-service sessions, and a Frequently Asked Questions sheet, and supporting site-based project officers during the preparation and the roll-out of the ORCs into their settings.

Phase 2

Summary

The multiple methods to address this phase's study objectives are a retrospective audit of current hospital observations charts and prospective audit of data following implementation of the selected ORC, user focus groups, observational field notes, and patient outcome data from routinely collected organizational data sources. After education and implementation of the ORCs in each site, clinical staff will use the charts routinely for observations for a minimum of 3 weeks, prior to data collection.

Retrospective and Prospective Audits

For the two audits, a 72-hour admission period was selected: February in the previous year (retrospective) and February in the current year (prospective). For each participating ward, 60 admission episodes will be audited at each site. Sunday, Monday, and Tuesday were selected as the audit period to include data related to activity occurring out of hours.

For the retrospective audit, observation charts in use prior to implementation of the ORC will be examined for rate of completion (number of complete sets of vital signs/number of charts audited), rate of recognition of abnormal clinical parameters (number of responses to an abnormal vital sign/number of abnormal vital signs identified on audit), and rate of triggered responses to a clinical deterioration (number of response teams triggered/number of clinical deteriorations identified on audit). Abnormal clinical parameters will be identified retrospectively using trigger criteria from the site-selected ORC. Data collection will also include hospital length of stay, location of discharge or transfer at end of admission, resuscitation status, and admission outcome.

During the prospective audit, the recently implemented ORCs will be audited for the same data as the retrospective audits, as well as extra items that will enable comparison with Phase 1 data on completion compliance according to the chart's general instructions.

Focus Groups

After ORC implementation and a period of routine use, project officers will conduct short semistructured focus group interviews with clinical staff. Participant consent will be gained prior to data collection, and the focus groups will be audio-recorded for transcription of de-identified verbatim comments. Focus groups will be scheduled during shift overlap, staff development sessions, and education forums with the aim of capturing the views of as many staff comments as possible. Sample questions will be provided to each site project officer.

Observations of Documentation Practice

Field observations are planned for the site-based project officers at negotiated times with each clinical area piloting the ORC, for a recommended minimum of six observation sessions per selected ward over at least 1-2 hours duration during the prospective data collection period. Observation sessions will range across different shifts on different days, to enable observation of activities related to use of the ORC in routine observation practices. Guidelines and a template for field notes will support project officers' observation of practices. Ward staff will be informed that observations related to ORC usage will occur using normal communication processes and visible placement of ward posters. Individual staff members are able to refuse participation during the observation periods, by negotiation with their ward manager. Project officer interaction with clinical staff is permissible during the observation period to clarify or ask a question.

Patient Outcome Data

To minimize data collection burden, patient outcome data will be collected using routinely collected organization-wide data systems for adverse events such as MET/arrest calls, unplanned

intensive care unit admissions, unexpected deaths, and length of stay. These data will be collected for the months of the retrospective and prospective audit periods, as well as an annual summary for the previous year when available from sites.

Data Management and Analyses

In Phase 1, the project officer at each site will assess all quantitative data for completeness, before data entry either locally or centrally (for de-identified paper-based user surveys). All data will then be cleaned and checked for errors centrally by the project manager prior to data analysis. Qualitative interview and field notes data will be transcribed for analysis at each site and transmitted to the research team for collation prior to analyses.

Quantitative data from the user survey and audit will be analyzed descriptively using frequencies and proportions, for each site individually and for the total sample. Transcribed qualitative data from the field notes of observations, debrief sessions, and open-ended questions from the user survey will be entered into NVivo and examined initially via content analysis (where appropriate including counts of categories of text) and then thematic analysis. Coding of text will use categories aligned with the project aims; for example, clarity of text, chart format and layout, comprehensiveness, ease of documenting, and capacity to trigger a response for a deteriorating patient.

For Phase 2, all site data will be sent to the research team for management and analyses. Audit data will be entered into Microsoft Excel, then cleaned and coded for analysis in SPSS (version 19). Patient outcome data will be sent in original form from the sites and then re-formatted and coded in Microsoft Excel. For quantitative data, frequencies will be examined for distribution. Descriptive statistics will be used to examine all data. For non-normal distributions of continuous data, medians and interquartile ranges will be used. Categorical data will be presented using proportions and frequencies.

Focus groups will be audio-recorded, and sound files sent to the research team for transcription. Project officer field notes will be typed up as Microsoft Word documents and also sent to the research team. Qualitative data will be entered into NVivo 9 and analyzed for descriptive content and emerging themes.

Ethical Considerations

For Phase 1, we plan to submit the proposal to each clinical site as a negligible/low-risk project, given that clinical staff (not patients) are study participants and the level of risk entailed during data collection. Informed consent will be sought from participants (all relevant clinical staff) for the survey, observations, and interviews, as required, prior to data collection.

For Phase 2, a proposal will be initially submitted to the Human Research Ethics Committee (HREC) of one selected lead site. Once approval is given, applications will be submitted to the HRECs of all other participating sites as required by the relevant jurisdiction for each site. The university HREC will then be approached for ratification. Clinical staff participants will be asked to provide informed consent for the focus groups, and observation periods by the project officer, using the provided participant information sheet and informed consent form.

Confidentiality of participant identity will be assured. All data will be stored as per national regulatory guidelines [18].

Results

Site selection and preparation, project officer training, chart selection and implementation, participant recruitment, and data collection has been completed and the analysis of these results are in progress.

Discussion

Study Summary

Clinical deterioration by adult patients in acute medical-surgical wards continues to occur, despite a range of systems and processes designed to minimize this risk. In Australia, the ACSQHC opted to develop a standardized template for adult observation charts using human factors design principles and decision-support characteristics to improve the detection of and response to abnormal vital signs.

This study aims to use a cross-sectional and a before-after design with multiple-methods data collection approaches to evaluate the implementation, clinical utility, and user acceptance of an observation and response chart for use with adult general medical-surgical patients in clinical sites across Australia. This pragmatic methodological approach aims to balance collection of a diverse dataset with a manageable level of participant burden, within the scope of the project tender set by the ACSQHC.

Limitations

A number of potential limitations with these proposed methods are evident. The use of an onsite project officer seconded from the local organization's staff will enable optimal communication and engagement with all relevant clinical staff. However, their

involvement as data collectors, including facilitation of focus groups, has the potential to influence participant responses or behaviors (possible Hawthorne effect). The 24-hour cycle of data collection in Phase 1 is designed to enable involvement and feedback from night-duty staff. While data collection periods will be short, these are proposed to minimize participant burden in busy clinical environments.

The before-after design in Phase 2 may limit causal inferences related to the chart implementation. While the use of control wards in sites may have improved interpretation, this latter design would also have other potential limitations, including differing ward cultures, case mix, and contamination bias.

Within the context of the chart design characteristics, modifications to parameter values and response levels will enable alignment with local site needs, policies, and practices. This process of flexible standardization provides site input, but perhaps not from front line staff (the users). As noted earlier, while the three non-ADDS charts did not have any simulation testing prior to this clinical testing, the design characteristics and sections, including the graphing section, were similar across all versions [12]. Different versions of the charts will not be directly compared to each other in sites; while this was not a study aim, it will limit ability to identify any user preference for a particular chart version.

Conclusions

This study plans to involve 10 sites from different Australian jurisdictions, including both public and private hospitals, with different levels of service and size, ranging from small rural facilities, to metropolitan and tertiary-level hospitals. This detailed description of the study methods will enable a comprehensive assessment of the clinical utility of these newly designed observation and response charts and will be useful for clinicians and researchers when planning and implementing similar studies.

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Authors' Contributions

DE conceived of the study, participated in its design and coordination, and drafted the manuscript. SM, LP, CD, MF, RG, RI, and MR all participated in the study design and coordination. EA participated in study coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

- ACSQHC:** Australian Commission on Safety and Quality in Health Care
- ADDS:** adult deterioration detection system
- EWSS:** early warning scoring system
- HREC:** Human Research Ethics Committee
- MET:** medical emergency team
- ORC:** observation and response chart

RRS: rapid response system

TTS: track and trigger system

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Original Paper

A Novel Approach to Realizing Routine HIV Screening and Enhancing Linkage to Care in the United States: Protocol of the FOCUS Program and Early Results

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Abstract

Background: The United States health care system remains far from implementing the Centers for Disease Control and Prevention's recommendation of routine human immunodeficiency virus (HIV) screening as part of health care for adults. Although consensus for the importance of screening has grown, innovations in implementing routine screening are still lacking. HIV on the Frontlines of Communities in the United States (FOCUS) was launched in 2010 to provide an environment for testing innovative approaches to routine HIV screening and linkage to care.

Objective: The strategy of the FOCUS program was to develop models that maximize the use of information systems, fully integrate HIV screening into clinical practice, transform basic perceptions about routine HIV screening, and capitalize on emerging technologies in health care settings and laboratories.

Methods: In 10 of the most highly impacted cities, the FOCUS program supports 153 partnerships to increase routine HIV screening in clinical and community settings.

Results: From program launch in 2010 through October 2013, the partnerships have resulted in a total of 799,573 HIV tests and 0.68% (5425/799,573) tested positive.

Conclusions: The FOCUS program is a unique model that will identify best practices for HIV screening and linkage to care.

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KEYWORDS

HIV; routine screening; testing; linkage

Introduction

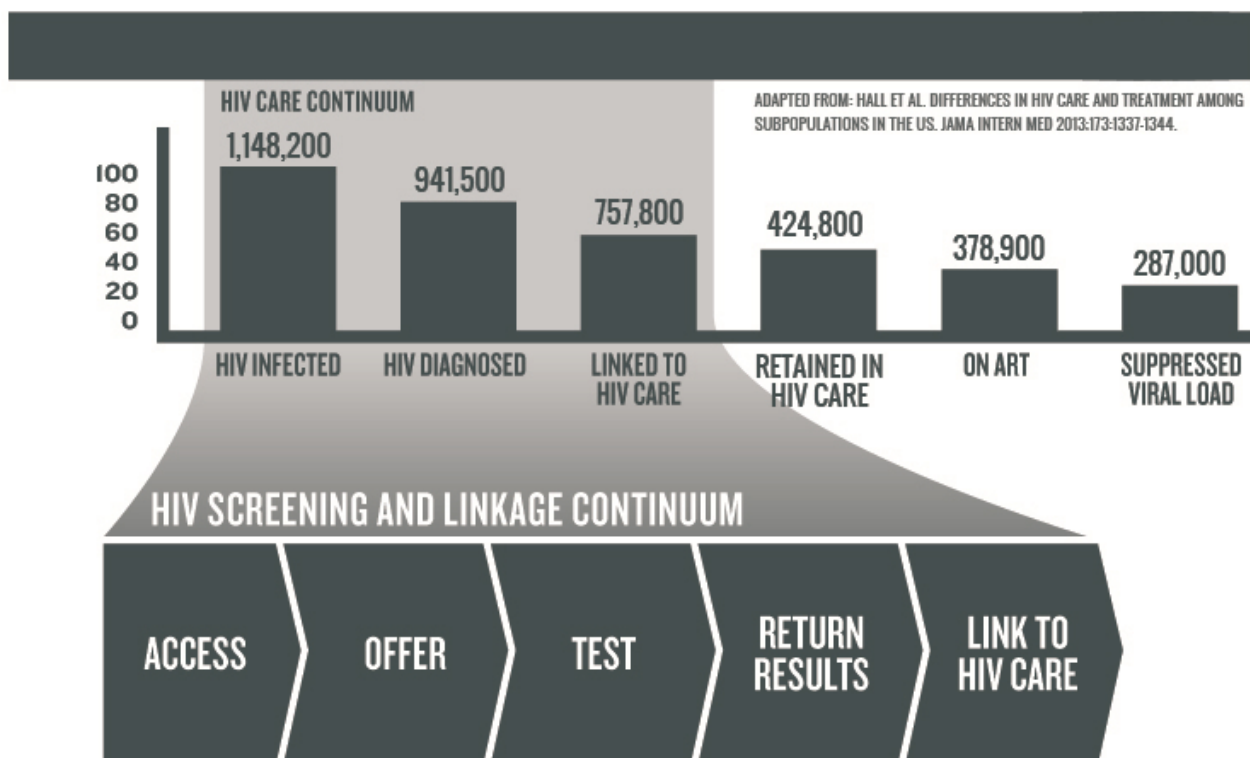
Nearly 8 years after the Centers for Disease Control and Prevention (CDC) recommended routine human immunodeficiency virus (HIV) screening for all Americans aged 13-64, the US health care system continues to struggle to make progress in meeting this important public health recommendation [1]. The scientific evidence supporting early diagnosis as a best practice has only become stronger [2,3]. In particular, the Cohen et al [2] study showed a greater than 90% reduction in HIV transmission to sex partners with earlier initiation of antiretroviral treatment. The Mugavero et al [3] paper emphasized how HIV testing is the prerequisite step into the continuum of sustained care and positive health outcomes for those living with HIV. Of persons in the United States who are living with HIV infection, 18% have not yet been diagnosed and one-third of those with a diagnosis are diagnosed late in the course of their disease [4,5]. Identifying innovative and robust approaches to reaching the large numbers of undiagnosed people living with HIV and doing so in a way that reaches them earlier in the course of their disease is key to making progress toward achieving viral suppression and providing its attendant clinical and prevention benefits. These approaches will not only need to substantially transform how we conduct HIV screening in clinical settings, but will need to address how the community as a whole responds to HIV screening and care.

There has been a steady accumulation of evidence and opinion that routine HIV screening is necessary to achieve the best individual and public health outcomes. A series of cost analyses beginning in 2005 suggested that routine HIV screening every 3 to 5 years would be justified for all but the lowest risk US adults [6-9]. Most recently, the United States Preventive Services Task Force (USPSTF) gave routine HIV screening a grade A recommendation [10].

The HIV care continuum from diagnosis to successful engagement with medical care to viral suppression is now an important conceptual framework guiding HIV prevention and care efforts in the United States [3,4,11]. We propose extending the concept of a care continuum to an HIV screening and linkage continuum. Using the framework allows us to describe and then act on barriers and facilitators in a series of steps necessary for routine HIV screening to occur (Figure 1).

Broadly, the screening and linkage to care components of the cascade require that people have access to and are offered HIV screening, that they get tested and receive the results of their test, and that they have a reliable link to HIV care. Appreciation of these essential elements provides a framework to address barriers and facilitators to the introduction and expansion of HIV screening in both clinical and community settings. The barriers may include lack of knowledge regarding routine screening recommendations, lack of awareness of community epidemiology of HIV, concerns about regulatory requirements for consent and pretest counseling, uncertainty regarding reimbursement, competing priorities for time, stigma associated with HIV and HIV testing and concerns about how people will respond to the offer of an HIV test [12-21]. The facilitators for routine screening in clinical and community settings include better recommendations, regulations, and health policies. Most states have already made considerable progress in eliminating or reducing pretest counseling requirements [22]. Expanded health care coverage that will be implemented through the Affordable Care Act is likely to increase the probability of a care visit [23]. The USPSTF grade A recommendation for HIV screening clears the way for reimbursement from all medical insurance plans eventually decreasing provider and patient concerns about reimbursement.

During this period of regulation and policy change, a major opportunity exists to develop and validate new approaches for improving routine HIV screening and linkage to care practices in the United States. This will require adopting new program models across multiple types of settings in the clinics and communities in cities that are most highly impacted by HIV. The amount of HIV screening in most clinical settings needs to increase by orders of magnitude to reach the standard of care set by the CDC and USPSTF recommendations. Additionally, not everyone routinely accesses medical care, including those who have had a previous HIV diagnosis. There remains a role for better community-delivered routine HIV screening and linkage to care coordination models. To accomplish such transformational changes in our clinical and community HIV screening programs, new approaches must be designed, efficiently evaluated, and disseminated. Promoting broader uptake will require closer to real-time sharing of these models to allow a rapid pace of knowledge application. This paper describes the overall approach of a large-scale and multi-component program that is specifically designed to address these needs.

Figure 1. Routine HIV screening and linkage to care.

Methods

FOCUS Program Overview

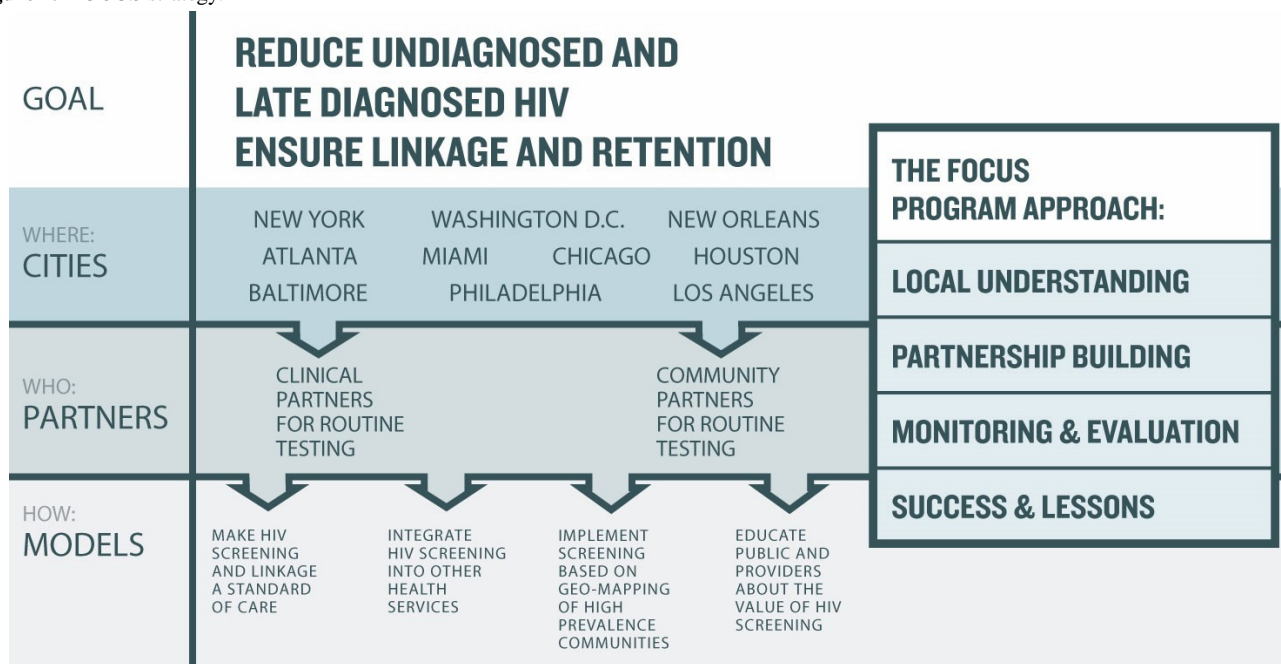
HIV on the Frontlines of Communities in the United States (FOCUS) was launched in 2010 and is a program of Gilead Sciences, Inc. The overall program goals are to create, implement, improve, and rapidly disseminate transformative approaches that make HIV screening a truly routine practice in both clinical and community settings and that improve linkage to HIV care for all persons living with HIV. The FOCUS program is implemented through a multilevel strategy (Figure 2).

The first level is “where” the FOCUS program is implemented: cities in the United States and communities within those cities that are most highly impacted by HIV infection. The second level is “who” implements the FOCUS program: partners within health departments and from clinical or community-based organizations who can be leaders of change in these cities. The third level is “what” should be implemented: model projects implementing components of the FOCUS program that are customized to their settings and all with the same overall FOCUS program goals. The FOCUS program uses a consistent approach to plan and coordinate activities by: building strategic

partnerships, conducting program monitoring and evaluation, and communicating program successes and lessons learned through informal and traditional mechanisms.

Working with a coalition of local health care and community leaders, a FOCUS Regional Lead in each city conducts a comprehensive assessment of the context for the program, translates the overall program model into city-wide plans of action, and builds strategic clinical and community partnerships that implement those plans (Multimedia Appendix 1). Partners with the potential to achieve FOCUS goals and who are leaders of broader change in their fields are invited to propose projects. The median project budget is approximately US\$175,000 for projects involving discrete activities that are implemented in a 12-month period. Funds support electronic medical records (EMR) modifications, data management, continuous quality improvement (CQI), personnel for linkage to care, upgrades to laboratory equipment, and dissemination of findings. If initial project objectives are met and if new and more expansive activities are proposed, partners can receive additional funding in subsequent years. Each 12-month project for a partner is counted separately for purposes of this report. FOCUS projects are specifically funded to support approaches that will ultimately be sustainable through other public investment or by third party reimbursement, such as health insurance.

Figure 2. FOCUS strategy.



FOCUS Data Collection, Monitoring, and Evaluation

All FOCUS partners report a common set of de-identified outcome indicators to a centralized database monthly (Multimedia Appendix 2). The requirement for standard and continuous data reporting produces a culture of data-driven decision making within FOCUS and among partners. The central data repository allows for quantitative comparisons between partner sites and project components that can be used to support continuous program improvement. Partners use the data in real-time and at facility-, unit-, or provider-level to continually monitor progress toward routine provision of screening, and modify their activities to achieve better results. Regional Leads use the de-identified data to monitor partner successes and support partners in making program improvements.

The FOCUS program uses an iterative process in which lessons learned from one partnership can be immediately applied to other similar partnerships, producing a real-time learning environment. This is facilitated by the frequency of outcome monitoring, the diversity of partnerships and the flexibility of the funding mechanism. Regional Leads facilitate the sharing of successful project components throughout similar settings and partnerships in their cities. Communication and networking among Regional Leads allows lessons learned in one city to be

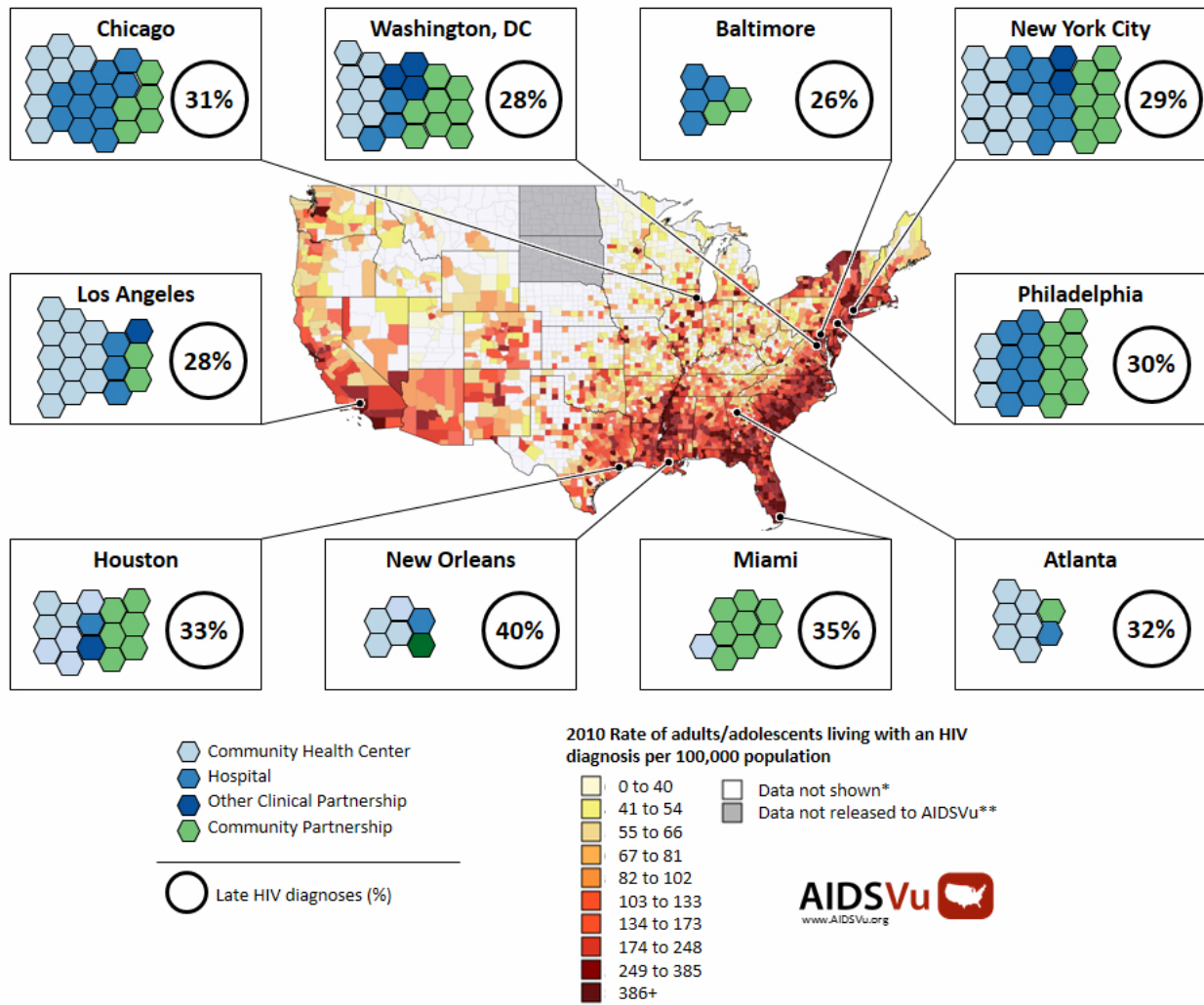
disseminated between cities. FOCUS uses program monitoring information to help set priorities for future partnerships and transform practices across existing partnerships. FOCUS partners also develop individual plans to disseminate lessons learned to others in their fields.

Results

Program Overview

The FOCUS program has been implemented in Atlanta, Baltimore, Chicago, Los Angeles, Houston, Miami, New Orleans, New York City, Philadelphia, and Washington, DC (Figure 3). These 10 cities represent 40% of the prevalent HIV diagnoses in the entire United States through 2010, and 36% of the new HIV diagnoses made in 2011 [24]. These cities also all have communities within them where greater than 1 out of every 50 people is living with HIV. Consistent with the national average, about 30% were diagnosed with HIV infection late in the course of their illness [25]. From program launch in 2010 through October 2013, 153 partnerships have been developed in the 10 cities. FOCUS partnerships have resulted in 799,573 HIV tests being conducted with 0.68% (5425/799,573) persons testing positive. These partnerships are of two types: clinical partnerships and community partnerships.

Figure 3. FOCUS partnerships by city.



Clinical Partnerships

Overview

All partnerships in clinical settings use the following components. We call these the “four pillars of routine HIV screening” (Figure 4 and Table 1).

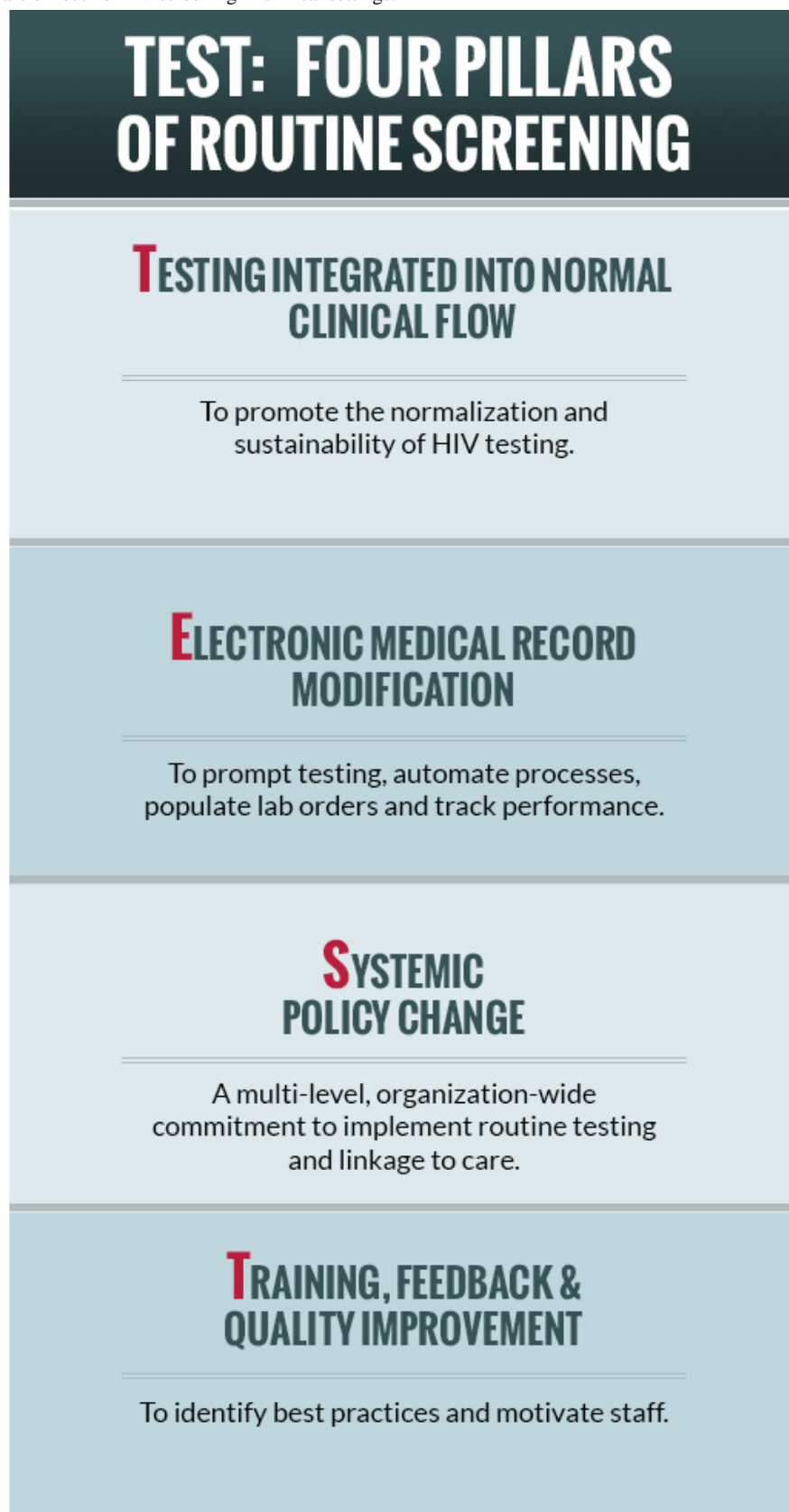
Figure 4. TEST: four pillars of routine HIV screening in clinical settings.

Table 1. Characteristics of FOCUS partnerships, 2010-2013.

Partnership setting ^a	Number of partnerships (%)	Cities ^b	Project components
Clinical			
Community health centers	57 (37)	ATL, CHI, HOU, LA, MIA, NOLA, NYC, PHI, DC	<ul style="list-style-type: none"> • Testing integrated into normal clinic flow • Electronic medical record modification
Hospitals	40 (26)	ATL, BAL, CHI, HOU, LA, NOLA, NYC, PHI, DC	<ul style="list-style-type: none"> • Systemic policy change • Training, feedback, and quality improvement
Other clinics	7 (5)	HOU, LA, NYC, DC	
Community	49 (32)	ATL, BAL, CHI, HOU, LA, MIA, NOLA, NYC, PHI, DC	<ul style="list-style-type: none"> • Community-delivered screening • Public and provider education • Community-led linkage to care
TOTAL	153		

^aPartnership types are defined as follows: Community health centers - provide comprehensive primary care, either grant-supported federally qualified health centers or non-grant-supported health centers certified by the Health Resources and Services Administration and the Centers for Medicare and Medicaid Services; Hospitals - provide general and specialized medical, surgical, or mental health services, can be on an inpatient or outpatient basis, and can be governmental, academic, and/or private institutions; Other Clinics - provide clinical services to patients but are not classified as health centers or hospitals, includes sexually transmitted disease, general wellness, and family planning clinics; and Community Partnerships - organization conducting activities outside of the clinical setting and in the community, includes community-based organizations, health centers, health departments, and academic institutions

^bCity Abbreviations: ATL - Atlanta, BAL - Baltimore, CHI - Chicago, HOU - Houston, LA - Los Angeles, MIA - Miami, NOLA - New Orleans, NYC - New York City, PHI - Philadelphia, DC - Washington DC

Testing Integrated Into Normal Clinic Flow

The best efficiencies for HIV screening in clinical settings are likely to be gained when testing is fully integrated into clinic flow. These changes not only reinforce provider perceptions that HIV screening is a routine part of care, but also improve the efficiency of the test offer. FOCUS partners develop ways to incorporate the offer and administration of the test into patient intake or triage processes. Missed opportunities for HIV diagnosis also continue to exist in other clinical settings where routine HIV screening should be available, such as at sexually transmitted disease and family planning clinics. The challenge has been ensuring seamless integration of HIV screening into these other health services. Rather than staffing and processes that make HIV screening something exceptional from other services offered, the same staff use existing infrastructure to conduct all of the health screening activities at these facilities. This is accomplished through simplified processes for making the test offer, obtaining appropriate documentation, collecting specimens, and conducting the HIV test. Full integration of the HIV test into normal clinical flow also increases the likelihood of long-term sustainability of HIV screening as it maximizes the use of indigenous clinic staff rather than staff dedicated solely to HIV testing. Some partners are using dedicated staff to help patients who test positive get linked to HIV care. Partners are implementing these changes through multiple methods such as standing physician orders for an HIV test, automating EMR reminders to offer/order a test, creating staff fact sheets and checklists for HIV screening, and conducting training with indigenous staff.

Electronic Medical Record Modification

EMR and laboratory information systems are now standard medical practice. Ensuring that HIV screening is fully integrated into these settings requires changes to the systems already in use. Modifications to these systems use a variety of approaches

to integrate the test offer and administration. Partners use these systems to create an algorithm to determine eligibility for the test offer, prompt staff to make offers, order HIV laboratory tests, record results, conduct CQI and support billing. Some systems have also been modified to trigger multiple opportunities to make the offer for HIV testing either at the same visit or in successive visits.

Systemic Policy Change

A critical step in making systemic improvements to HIV screening programs in clinical settings is changing perceptions of key leadership, such as the chief executive officer, chief medical officer, chief nursing officer, laboratory director, chief operating officer, and chief of risk management. Unlike models that offer specialized or targeted HIV testing and linkage to care services, integration into routine clinical practice requires an organization-wide commitment from leadership and clinic staff, and involves a continuous process of uncovering barriers and developing solutions to change the perception of HIV testing from being a specialized service to a routine one. In addition, FOCUS partners are establishing improved policies and procedures for ensuring that diagnosed persons are effectively linked to HIV care. Partnerships are engaging with leadership and clinic staff through multiple methods, such as policy briefs, baseline data assessments, cost analyses, leadership meetings, and provider champions.

Training, Feedback, and Quality Improvement

Systematic program improvement relies on collecting and effectively using key indicators to continuously monitor progress and outcomes. The use of data to make program improvements is especially important for implementation of routine HIV screening programs in clinical settings. To ensure that HIV screening is being implemented in a truly routine manner, these systems must be able to track and monitor unique patient visits, eligibility for testing, test offers, tests conducted and linkage to

care for those identified as positive. All clinical partners are required to have a monitoring and feedback system that tracks these elements as an integral part of their program. These CQI systems allow partners not only to collect monitoring data, but incorporate plans for routinely sharing information with clinic leadership, providers, and staff. An integral part of these projects is to also institute staff and provider training, incorporating feedback from the monitoring systems. When opportunities for improvement are evident, the CQI process uses detailed plans of action to make improvements. The ultimate purpose of CQI is to promote full scale-up and sustainability in these settings.

In addition to the four pillars of routine screening, partners are also encouraged to critically consider the type of HIV test that they employ. HIV test technologies have been continually evolving, serologic assays are becoming increasingly sensitive, and new testing platforms have been developed that allow for large throughput of samples in the laboratory. This may be particularly important in HIV screening programs in clinical settings that not only require a rapid return of a test result but may also be challenged with large numbers of HIV tests. These large-scale HIV screening platforms allow better integration into the routine laboratory practices of large-volume medical facilities by using blood specimens that are already being collected for other purposes. The newest generation of these platforms also have the added benefits of using 4th generation HIV serologic assays that are compliant with new HIV screening algorithms for laboratories and detect HIV infection earlier than

most other point-of-care rapid tests and laboratory-based tests [26,27]. They also allow confirmation of an HIV diagnosis to be made in a single visit, which may facilitate more timely linkage to HIV care. Several partnerships in large-volume clinical settings are just now implementing these new test technologies to improve routine HIV screening.

Partnerships in clinical settings include 57 community health centers in 9 FOCUS cities (Table 1). These community health centers have conducted 257,869 HIV tests and had 0.54% (1398/257,869) of persons test positive (Table 2). Partnerships in clinical settings also include 40 hospital systems in 9 cities. These hospitals have conducted 385,667 tests and had 0.72% (2793/385,667) of persons test positive. The program has also built partnerships in other clinic settings that integrate HIV screening and linkage to care into other health services through 7 partnerships in 4 cities. These other clinics have conducted 54,798 tests and had 0.52% (286/54,798) of persons test positive. Using data to support project improvements between and within partnerships is especially important in identifying and replicating aspects of routine screening in clinical settings that are most effective at reaching interim program goals. An example of this iterative improvement process for FOCUS clinical partnerships is presented in Textbox 1. In addition to sharing lessons within the FOCUS program, partners in clinical settings have also begun to disseminate project outcomes and details of their individual models. Clinical partnerships have resulted in 15 conference presentations and 1 journal publication about their projects [28-43].

Table 2. FOCUS testing outcomes, 2010-2013.

Partnership setting	Number of tests	Number of persons tested positive	% of persons positive	Partner presentations, publications, and media
Clinical				
Community health centers	257,869	1398	0.54	28-34, 43
Hospitals	385,667	2793	0.72	35-39, 43
Other clinics	54,798	286	0.52	40-42
Community				
Total	799,573	5425	0.68	44-54

Textbox 1. Iterative improvement and dissemination in clinical settings.

The iterative improvement process is best illustrated by two early FOCUS partnerships to implement routine HIV screening in large, multifacility, community health centers. AltaMed Health Services based in Los Angeles implemented first and learned early on that success depended upon the engagement of executive leadership through a CQI process. Leadership authorized modifications to the EMR to designate the eligible patient population, prompt offers, and track tests. This resulted in a substantial increase in HIV testing at AltaMed. They were also able to demonstrate improvements in HIV testing after implementation of mandatory staff training about routine HIV screening. Some months later, Urban Health Plan in New York City adapted its already well-developed CQI program to also address routine HIV screening. Drawing upon AltaMed's experience, Urban Health Plan modified the EMR and tracked offers and tests not only by facility but also by provider. Provider-level tracking and a weekly review of results identified good outcomes as well as pockets of resistance, which were then addressed through provider-level coaching about routine HIV screening. Both partnerships used their CQI data to demonstrate that the desired scale and normalization of HIV testing was best achieved through laboratory-based testing integrated into standard clinical practices. These processes, methods, and tools were shared with all FOCUS partnerships in clinical settings and were further adapted and refined. This program model is now institutionalized for FOCUS as "TEST: Four Pillars of Routine Screening," and is incorporated into all new proposals for partnerships in clinical settings.

Community Partnerships

Overview

Partnerships in community settings employ varying combinations of activities related to routinely screening persons for HIV infection and ensuring linkages to HIV care. Partnerships implemented the following components.

Community-Delivered HIV Screening

HIV testing opportunities in community settings not only reach persons who are not engaged with health care, but can also reduce stigma and change attitudes regarding HIV and HIV testing in all settings. Partners employing this model use

Textbox 2. Community-delivered HIV screening.

In October 2010, Family Medical Counseling Services, Inc implemented a novel HIV testing strategy at the Department of Motor Vehicles (DMV) in a highly impacted area of Washington DC. This DMV office provides driver's license and automobile tag services to over 150,000 residents annually. Dedicated project staff introduce the opportunity to test to the entire waiting room at frequent intervals and discuss the importance of routine HIV testing. Everyone awaiting DMV services is offered a test. Rapid HIV testing is fully integrated into the flow of the DMV visit usually while people are waiting for services, is conducted in a private office inside the DMV, and all who test positive are immediately referred to care and support services. In 2011, this testing strategy was expanded to the Income Maintenance Center (IMC), the government office that provides residents with public benefits including food stamps, financial assistance, and health insurance services. The project has the primary goals of promoting and increasing access to HIV testing among residents in the high prevalence area east of the Anacostia River in Southeast, DC. Important lessons learned from these programs is that it is acceptable, feasible, and sustainable to implement a fully integrated HIV screening program in a high volume public services office if you work closely with service center staff, there is adequate space available to conduct confidential testing, and the duration of the service center visit will enable time for the entire HIV screening process. Through October 2013, the DMV and IMC screening program has conducted 25,361 HIV tests and had 0.56% (143/25,361) of persons test positive.

Community-Led Linkage to Care Coordination System

HIV screening programs have traditionally relied on specialized linkage to care service providers or passive referrals to HIV care and treatment. FOCUS partners have made multiple improvements in their linkage systems by adopting active approaches to link people to care and treatment. Though all partners are required to make improvements in linkage to care processes for people who test positive in their own programs, some novel FOCUS community partnerships act as coordinators for linkage to care activities for everyone who tests positive in their communities. These projects coordinate linkages from multiple places that do HIV testing and to multiple places that provide HIV care in the community. These projects include providing assistance to schedule the first medical care appointment, obtaining better contact information to allow ongoing support of diagnosed persons, ensuring that the first and subsequent medical appointments were attended, and establishing more effective collaborations with infectious disease or HIV primary care providers.

Public and Health Care Provider Education about HIV and HIV Testing

To reduce stigma and normalize attitudes regarding HIV and HIV testing, some community partners implement projects specifically designed to educate patients or providers about HIV. Academic partners are developing and delivering curriculum and practical experiences in HIV screening for students and midcareer health care professionals, including physicians, nurses, dentists, and pharmacists. Health departments are creating and disseminating tools to help health care providers understand HIV screening laws and to simplify offers, testing, and interpretation of test results. Other partners are producing

geographical mapping tools such as AIDSvu.org and local HIV program data to identify communities that are most highly impacted by HIV and identify venues for community-delivered HIV screening. Unlike many other outreach testing projects that conduct more targeted HIV testing, FOCUS partners offer a test to everyone encountered in these settings. These projects use a number of innovative approaches, such as retail-outlet and pharmacy testing, testing at high-volume public service centers like department of motor vehicle offices, and door-to-door testing in the neighborhoods targeted through epidemiologic mapping. An example of a community-delivered HIV screening project is presented in [Textbox 2](#) [44,45].

information campaigns with messages about the availability of HIV screening options, and reinforcing messages that HIV infection in these highly impacted communities is just as much about where you live as it is about what you do (ie, not just about risk-based HIV screening).

The FOCUS program engages 49 community partnerships across all 10 cities to offer HIV screening in unique settings and support innovative stakeholder engagement and public education campaigns ([Table 1](#)). Organizations conducting HIV screening in the community have conducted 101,239 tests and had 0.94% (948, 101,239) persons test positive ([Table 2](#)). FOCUS partnerships in community settings have resulted in 10 conference presentations and 1 peer-reviewed journal article [44-54].

Discussion

Improvements in Routine HIV Screening are Needed

HIV transmission continues at a steady rate in the United States during an era of new testing guidelines, effective HIV prevention strategies, and advances in care and treatment: an estimated 48,000 people in the United States are newly infected each year [55]. Approximately 200,000 people living with HIV are not yet diagnosed [4]. The scope of the linkage and retention in care problem is also large, with approximately 500,000 people living with HIV in the United States who know they are infected, but who are not currently accessing HIV medical care [4]. Despite strong and consistent recommendations for routine HIV screening as part of medical care in the United States [1,10], routine screening is not yet a realized standard of care in most clinical settings. In the first 5 years after the CDC recommendation for routine HIV screening in clinical settings

there have been statistically significant but practicably insufficient increases in HIV testing; still more than 50% of adults have never had an HIV test [56]. The rate of ever having an HIV test only grew 9% from 2000 to 2010. By sustaining this level of change, it would take another 40 years to achieve testing rates of more than 80%. The President of the United States has identified an urgent need for a renewed focus on both HIV screening and linkage to care programs [11].

Current Implementation of FOCUS

The FOCUS program is attempting to address these needs by being a catalyst and proving ground for these transformational changes. The FOCUS program has established 153 partnerships in 10 highly impacted US cities, resulting in almost 800,000 HIV tests and more than 5400 HIV diagnoses. More detailed and comprehensive program evaluation activities are still underway, but clinical and community partners are already producing interim findings and project component details in the form of media stories, conference presentations, and peer-reviewed papers.

FOCUS partnerships are creating models that are intended to be practical to implement, be sustainable in the long term, and be replicable in similar settings. It should not be discounted that early experiences highlight the broad scope of changes and the intensive resources needed: fully integrating HIV screening into clinic flow, improving provider training, altering public perceptions of HIV screening, appropriately using new HIV testing technologies, maximizing the potential of EMRs, streamlining public laws and policies, and reducing stigma toward those living with HIV. All of these require significant investment of human and infrastructure resources to bring about sustainable change.

The FOCUS program fills a gap in existing funding mechanisms and sources. FOCUS partners are more than demonstration projects to illustrate improved incremental approaches to implementing routine HIV screening. Previous demonstration projects often resulted in improvements in local practices, but dissemination and propagation of best practices was less predictable. The FOCUS program includes mechanisms for rapid feedback and sharing of best practices, increasing the impact of lessons learned by promoting timely dissemination to other partners. The FOCUS program is also different from implementation science by nature of the quick cycles of implementation, evaluation, and change. Plans are underway to conduct formal program evaluations and create toolkits based on FOCUS project components. These evaluations and toolkits will also help affect broader systems change for routine HIV screening and linkage to care.

Future of FOCUS

The FOCUS program is a unique model for how nongovernmental funding sources can engage in dynamic and evidence-based projects to identify best practices for HIV screening and linkage to care. The FOCUS program will increase the volume of screening directly supported by its funding, but the primary goal is to find ways to transform existing systems and achieve sustainable change through reducing barriers and capitalizing on innate system strengths. The ultimate success of the FOCUS program will lie in the commitment to an overall vision of excellence, data-driven decision making, a shared learning environment, and a culture of continually seeking transformative innovation. Importantly, the success of the program will rely upon the high level of commitment and expertise of the wide variety of FOCUS partners on the frontlines of the US HIV epidemic every day.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

FOCUS Plan of Action Template.

[PDF File (Adobe PDF File), 280KB - [resprot_v3i3e39_app1.pdf](#)]

Multimedia Appendix 2

FOCUS Monitoring Indicators.

[PDF File (Adobe PDF File), 96KB - [resprot_v3i3e39_app2.pdf](#)]

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Abbreviations

CDC: Centers for Disease Control and Prevention
CQI: continuous quality improvement
DMV: department of motor vehicles
EMR: electronic medical records
FOCUS: Frontlines of Communities in the United States
HIV: human immunodeficiency virus
IMC: income maintenance center
USPSTF: United States Preventive Services Task Force

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Original Paper

A Web-Based Program for Informal Caregivers of Persons With Alzheimer's Disease: An Iterative User-Centered Design

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Abstract

Background: Web-based programs have been developed for informal caregivers of people with Alzheimer's disease (PWAD). However, these programs can prove difficult to adopt, especially for older people, who are less familiar with the Internet than other populations. Despite the fundamental role of usability testing in promoting caregivers' correct use and adoption of these programs, to our knowledge, this is the first study describing this process before evaluating a program for caregivers of PWAD in a randomized clinical trial.

Objective: The objective of the study was to describe the development process of a fully automated Web-based program for caregivers of PWAD, aiming to reduce caregivers' stress, and based on the user-centered design approach.

Methods: There were 49 participants (12 health care professionals, 6 caregivers, and 31 healthy older adults) that were involved in a double iterative design allowing for the adaptation of program content and for the enhancement of website usability. This process included three component parts: (1) project team workshops, (2) a proof of concept, and (3) two usability tests. The usability tests were based on a mixed methodology using behavioral analysis, semistructured interviews, and a usability questionnaire.

Results: The user-centered design approach provided valuable guidelines to adapt the content and design of the program, and to improve website usability. The professionals, caregivers (mainly spouses), and older adults considered that our project met the needs of isolated caregivers. Participants underlined that contact between caregivers would be desirable. During usability observations, the mistakes of users were also due to ergonomics issues from Internet browsers and computer interfaces. Moreover, negative self-stereotyping was evidenced, when comparing interviews and results of behavioral analysis.

Conclusions: Face-to-face psycho-educational programs may be used as a basis for Web-based programs. Nevertheless, a user-centered design approach involving targeted users (or their representatives) remains crucial for their correct use and adoption. For future user-centered design studies, we recommend to involve end-users from preconception stages, using a mixed research method in usability evaluations, and implementing pilot studies to evaluate acceptability and feasibility of programs.

KEYWORDS

usability; caregivers; Alzheimer's disease; psychoeducational program; psychological stress inclusive design

Introduction

Background

Psycho-educational interventions have shown benefit in relieving the burden of caregivers of people with Alzheimer's disease (PWAD), and associated manifestations of caregivers' distress [1,2]. However, these programs are often implemented on-site in individual or group sessions, and may thus not be available for many caregivers who are overwhelmed or isolated, are unwilling to resort to available community help [3], live in remote regions [4], or are still in active life.

With the proliferation of information and communication technologies, there has been a growing interest in developing distance-based interventions that might be useful for this particular population of caregivers. Internet-based interventions have shown promising improvements in psychological [5-7], and physical outcomes [8]. Among these interventions, Web-based programs have shown to better respect the caregiver's privacy and respond to availability issues than telephone-based interventions [9]. Moreover, the recent assessment report of the French Alzheimer's Plan 2013 [10] recommends the use of Web-based interventions in order to inform and support family caregivers.

User-Centered Design Approach

However, one limitation of Web-based programs resides in the obstacles caregivers face adopting and making correct use of them [11]. The majority of caregivers of PWAD are over 65 years of age [12]. The typical changes accompanying aging (sensorial, perceptive, cognitive, and motor age-related declines), make it even more difficult for them to interact with technological systems [13]. Moreover, most of the older adults are also limited by their narrow experience with the Internet and by the lack of usability of some websites [14]. These aspects have been taken into consideration during the development process of our Web-based program.

In fact, the user-centered design approach fosters the conception of accessible products, and targets the needs of end users. Usability testing is a user-centered design method, which aims to identify the problems users are confronted with when using (technological) products, and to find the means of solving them [13]. To our knowledge, despite the benefit of usability testing in favoring the adoption and correct use of Web-based programs intended for caregivers of persons with dementia, few authors reported the use of this method or the adoption of a user-centered design approach in the development of their programs [6]. In contrast, usability studies are more frequent for programs

targeting other populations, such as adolescents with overweight [15], or patients with chronic obstructive pulmonary disease [16]. To our knowledge, this is the first published work describing the user-centered design applied in the development of a program for caregivers of PWAD before it is tested in a randomized clinical trial.

The Present Study

In fact, we aimed the application of user-centered design approach in developing a fully automated Web-based psycho-educational program called Diapason. This program was adapted from a face-to-face intervention, developed and tested by our team in order to reduce or prevent caregivers' stress [17]. The Diapason program delivers: (1) disease information in twelve weekly sessions, (2) relaxation guidelines with training videos, (3) caregivers' testimonials, and (4) stimulation activities for the relatives. This program is available in a free fully automated computerized and password-protected website. In this paper, we describe the iterative process that allowed for the adaptation of the program's content and design.

Methods

Design

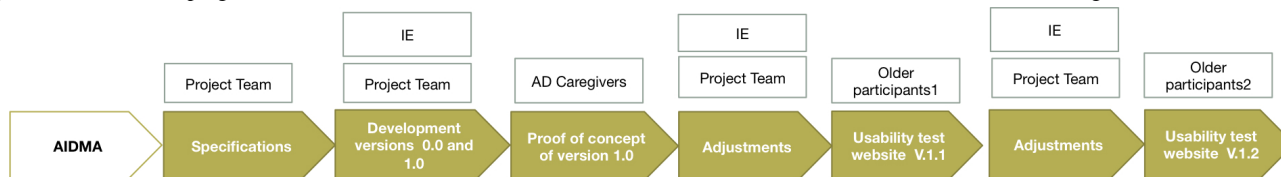
This was an exploratory-descriptive study, which consisted of a double iterative design allowing for the adaptation of the content and usability of the website. A group of health professionals (project team) participated in the iterations for determining the content, layout, and program design in the different stages of development through the workshops. In parallel, we conducted a proof of concept with caregivers and two usability tests with healthy older adults. The latter were based on a mixed research method with a convergent parallel design. Indeed, the protocol of the usability tests consisted of qualitative and quantitative data that were collected concurrently, but analyzed separately, and finally merged during the interpretation [18]. We used this method in order to obtain a more comprehensive analysis of data, and to raise the reliability of results. All the participants gave their written informed consent prior to their inclusion in the study.

Diapason Program Development Process

Overview

The program development process took place from 2009 to 2011 and included the following component parts: (1) design and development of the first two versions of the website, (2) proof of concept, and (3) two iterative usability tests (Figure 1 shows the development process).

Figure 1. Face-to-face program, AIDMA=Aide dans la maladie d' Alzheimer, AD=Alzheimer's disease, IE=Informatics engineer.



Project Team Workshops

Participants

The project team comprised twelve health care professionals and researchers who participated in the regular meetings, 2 physicians, 8 psychologists, and 1 sociologist, all from the same geriatric department, as well as an informatics engineer.

Procedure

Throughout the whole development process, two psychologists (FM or VCL) moderated and conducted regular workshops in an informal setting with the project team. During each workshop, their specifications and recommendations were collected by one of the moderators. Based on their feedback, the informatics engineer built the website prototype (V.0.0), and its successive versions for the proof of concept and usability tests.

In addition, the project team analyzed the offline prototypes during the workshops. The analyses were focused on the following criteria inspired from usability guidelines [13,14,19,20]: (1) avoiding technical terminology (neither medical- nor informatics-related); (2) ameliorating accessibility for nonexperienced users, providing a familiar look (eg, looking like a printed notebook); (3) improving readability (including font size and contrast); (4) facilitating navigation (eg. providing visual cues); and (5) adapting the content to the target users (privileging condensed, clear, quick, and easily accessible information).

Proof of Concept

Participants

We recruited six informal caregivers of PWAD who attended the memory clinic, including three children, mean (SD) age

50.3 (12.4) years, and three spouses, mean (SD) age 73.4 (7.5) years, having at least once used the Internet. A purposive sampling approach was used to recruit the same number of children and spouses. Purposive sample techniques involve selecting certain units based on specific purposes rather than randomly. These techniques are used when the researcher wants to “set up a comparison between different types of cases”; it allowed us to compare the opinions of younger and older users about the program.

Procedure and Evaluation Tools

Each participant received a clear explanation of the program’s aim, and then browsed the Diapason website offline v1.0. After that, a semistructured in-person interview carried out by a psychologist (≈ 40 minutes) was recorded in order to evaluate the opinions of caregivers. Semi structured interviews have a flexible and fluid structure, organized around an interview guide [21]. Questions regarding website usability and appearance were covered in the course of the interview.

First Usability Testing (Test 1)

Participants

As mentioned in the Introduction, since older people experience more difficulties with Internet use than other caregivers, we targeted them for usability testing. In order to avoid the learning bias, we recruited two different groups for each prototype version. There were 16 self-reportedly healthy persons 60 years and older (age mean 73.81, SD 7.03), having at least once used the Internet, that were recruited from three seniors associations in Paris. Sociodemographic information is summarized in Table 1.

Table 1. Sociodemographics of usability test participants.

Characteristics	Test 1 mean (SD) or n (%)	Test 2 mean (SD) or n (%)
Participants gender		
Male	4/16 (25)	2/15 (13)
Female	12/16 (75)	13/15 (87)
Participants age (years)	73.81 (7.03)	72.12 (7.03)
Internet experience (years)	8.32 (6.79)	8.91 (8.07)
Frequency of Internet use (days per month)	25.31 (10.22)	22.33 (10.32)

Procedure and Evaluation Tools

A research psychologist conducted a one hour individual usability test with each participant. The session was divided into four steps:

1. The participant filled out a questionnaire on sociodemographic data, Internet experience, and the monthly frequency of Internet use.
2. The participant was asked to follow written instructions (Textbox 1) of navigation on the offline version of v1.1 (Figure 2 shows this version) using a “think aloud” method

- [22]. In the “think aloud” method, which is common in usability testing, the users are asked to think aloud while using the system, allowing the evaluator to understand what they are doing and the reasons for their actions [13]. The five tasks were selected to cover the main functions of the website. The test sessions were video-recorded for a behavioral analysis. Moreover the psychologist noted the participant’s mistakes, difficulties or comments, and avoided to interfere with the evaluation.
3. The participant’s opinions of website usability were assessed with a five point Likert scale (0= negative to 4=

positive) designed by our team (VCL). The survey evaluated five topics: (1) overall impression about the website; (2) easy-to-use perception; (3) pleasant to use perception; (4) coherence of website layout; and (5) satisfaction with the website design (font, colors).

4. At the end, the participant was asked to answer a semistructured interview on the following topics: (1) positive and negative aspects of the website, (2) difficulties when using the website, (3) discomforting situations during navigation on the website, and (4) advice to improve the appearance and design.

Textbox 1. Five step usability test.

1. Please enter to the website: www.etraudiapason.com
 - Username: *Participant*
 - Code: 123456
 - Go back to the home page
2. Go to the session “*Managing the caregivers stress*”
 - Watch the video “*caregiving-related stress*” and change to full-screen
 - Go back to the home page
3. Search the glossary
 - Read the meaning of the word “*hippocampus*”
 - Go back to the home page
4. Go to the stories
 - Read the story of “*Lucia*”
 - Go back to the home page
5. Go to the forum
 - Post the message: *I’m using Diapason*
 - Go back to the home page

Second Usability Testing (Test 2)

Participants

We recruited 15 healthy volunteers over 60 years old, age mean 72.12; SD 7.03, through three seniors associations in Paris. They had at least once used the Internet. Sociodemographic information is summarized in [Table 1](#).

Procedure and Evaluation Tools

With the second usability test, we evaluated the offline v1.2 ([Figure 2](#)). The protocol was identical to the first usability test.

Analysis Methods

Qualitative data from the workshops (ie, moderator’s notes), the proof of concept (ie, interviews), and the usability tests (ie, interviews and mistakes, difficulties or comments; observed

and collected by the evaluator) were analyzed based on the thematic analysis method [23]. After being familiarized with data JW and VCL coded the relevant extracts of material concurrently. Then, they analyzed the themes based on the recommendations of various usability authors [13,14,24,25]. Finally, they corroborated the pertinence of the selected topics, comparing them with initial verbatim.

Assisted by the software “The Observer XT” and an observation grid, two trained psychologists (VCL and JW) collected, coded, and analyzed videos of usability tests. We measured the frequency of mistakes, requests for help, and the duration of task performance.

Finally, we analyzed the satisfaction survey results using descriptive statistics.

Figure 2. Diapason website program versions.



Results

Participants

In total, 49 persons were involved in the Diapason program development: 12 health care professionals, 6 caregivers, and 31 healthy older adults. The development process resulted in four successive website versions as shown in Figure 2 for which the qualitative results of the iterative design are provided in Table 2.

Qualitative Results

Project Team Workshops

The results of the first workshops showed that most professionals were motivated by the new project. They proposed interesting and creative ideas to develop the Web-based program. They stated that the Diapason program should be made easily and rapidly accessible to overwhelmed caregivers who may have only fifteen or twenty minutes to spend with the

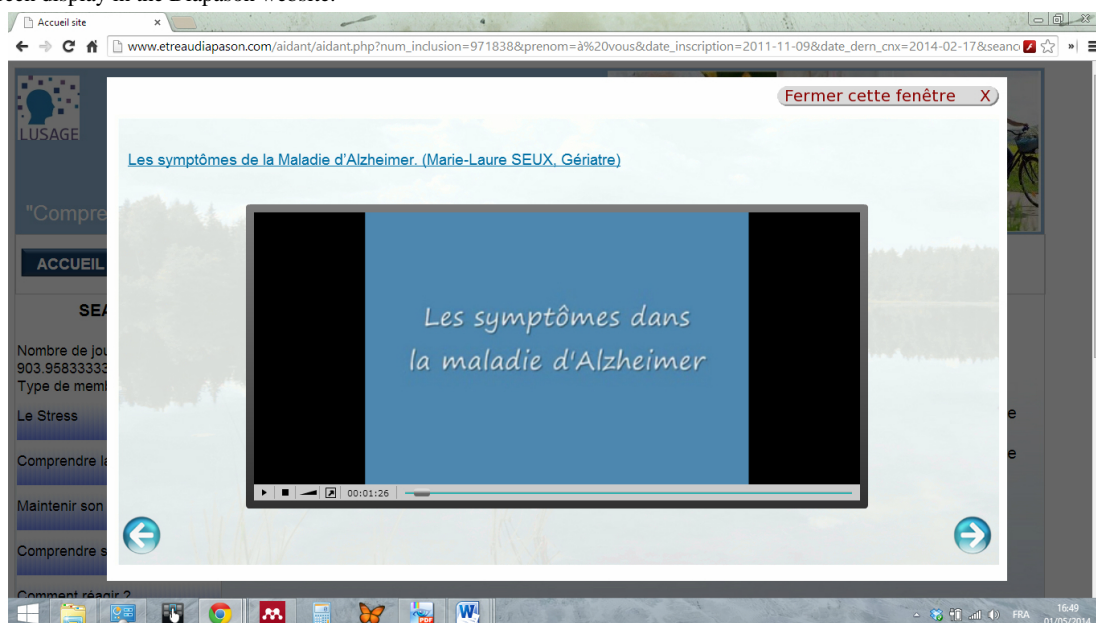
program. Some professionals also expressed concerns about the suitability of Internet use for caregivers, since most of them were spouses of patients and likely inexperienced with this technology. Some also thought that computers might increase caregivers' isolation.

Based on the criteria selected by the team (described above in the Procedure of Workshops), the website v0.0 was not retained. The content was too long, complex, and technical for nonprofessionals. The appearance was dark, sad, and stigmatizing (Figure 2). As for v1.0, the project team suggested the use of a more "common" language for the button sections. They also recommended using a "light box" effect, to facilitate navigation (Figure 3 shows this display). Concerning v1.1, the team found "My journey" functionality unnecessary or infeasible. It was also suggested to add a "Relaxation training" in the program. As regards v1.2, the professionals supervised the consistency of changes made by the informatics engineer on the website following the demands of end-users, and prioritized them, based on their feasibility and relevance.

Table 2. Qualitative results.

Website version	Category	Problem reported	Actions and/or solutions
PT^a workshops			
0.0	Readability	Content too complex, using technical jargon	Contents were simplified, avoiding medical or informatics jargon
		Content too long, adapted for professionals caregivers	Contents and the layout were reedited
	Appearance	Black and gray colors, photo suggestive of sadness	The website was redesigned with “flashy” colors
Proof of concept and PT^a workshops			
1.0	Readability	Low contrast between characters and background of some website pages	The color of website background was modified
		Font size too small (12 point)	The font size was increased (16 point)
		Unfamiliar terminology	The terms were replaced, eg, “resources” by “document”, “search engine” by “glossary”, “me/he/she” by “life’s testimony”, among others
	Ergonomics	Complex actions to access the “sessions”	Action was simplified
Usability testing #1 and PT^a workshops			
1.1	Ergonomics	Participants clicked twice on the hyperlink, but flash screen closed with the second click	Explanation in the Internet and printed user manual
		Lack of an icon to close the flash screen	Add the icon “close this window”
		Small characters at the forum section	[no quick solution]
		“Send the message” option is at the bottom of the website, and requires use of the vertical scrollbar	[no quick solution]
		Some participants are not familiar with video-player icons	Explanation in the Internet and printed user manual
Usability testing #2 and PT^a workshops			
1.2	Ergonomics	Dimensions of the website vary depending on Internet browser and computer models	[no quick solution]
	Navigation	Hyperlinks text was unfamiliar for some of participants	Explanation on the Internet and in a printed user manual

^a PT = project team

Figure 3. Screen display in the Diapason website.

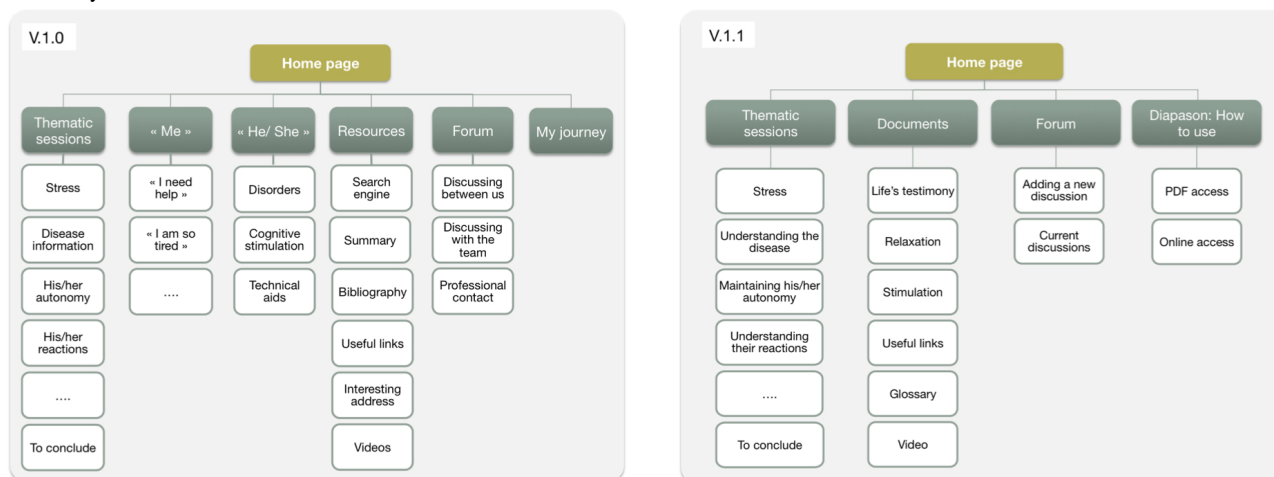
Proof of Concept

Overall Opinion of Caregivers

The caregivers found the website prototype (v1.0) clear and understandable. All of them, and especially the PWAD's spouses, appreciated the aims, the topics, and the website's layout. Although the participants thought the Web-based program likely to be useful for isolated caregivers, most of them underlined the need to communicate with professionals and to maintain face-to-face contact.

The suggestions to change the look (adding photos and modifying colors) were implemented in the following version

Figure 4. Layout for versions 1.0 and 1.1 - PDF=Portable document forwards.



Font Readability

The younger caregivers found the font size too small and thought it would constitute an obstacle for older users. By contrast, older participants did not raise this issue, but reported that some pages were difficult to read due to the lack of contrast between the background and the font. In the subsequent version (v1.1) the font size was increased and the contrast enhanced.

Ergonomics

To access the sessions, the user had to click on a button, and then confirm their choice by clicking on another one. This condition was simplified.

Simplified Layout

Based on the project team and on caregivers' suggestions, the website's layout was simplified (Figure 3). The version v1.1 and the final version only offered three main sections: (1) thematic "sessions", (2) a "forum", and (3) the "documents" providing access to other content (eg, relaxation or glossary).

Unfortunately the option "contact a professional" and the videoconferencing options were not implemented, owing to a lack of resources. Moreover, the section "My journey", a private diary for caregivers, was removed because the system could not encrypt the data.

Usability Test of v1.1

In this version, the overall program content was added to the website. Moreover, the readability improvements performed

(v1.1). Moreover, the caregivers pointed out important usability issues.

Unfamiliar Terminology

Although the project team aimed to avoid jargon (from informatics or medical areas), some of the terms used remained confusing for the participants in this version. For instance, the "Resources" button (ie, "Ressources" in French), giving access to additional sections (eg, relaxation training, glossary, etc), was understood as giving access to financial help. Consequently, the website was reorganized, and potentially confusing words or expressions were replaced by more commonly used website terminology (Figure 4 shows this layout).

during the proof of concept phase were appropriate, as no participant reported any visual discomfort while browsing the website (except for the forum, as described in this section). Concerning the easy-to-learn perception, many participants asserted that they would have performed better if they had used the website more than once.

Using the website would be easy provided I received training or that I spend more time using it. [Mrs. H, 71 y/o]

However, various ergonomics issues were identified. Although the website home page was kept accessible using a script (jQuery Superbox) to display a screen with a light box effect (Figure 3), most participants did not know how to go back to the previous page.

To go back to the home page sometimes I had to click in a grey zone or sometimes click on the close button, this is not practical. [Mme GG, 69 y/o]

To correct this, we added an icon at the top right of the screen with the message "Close this window" (in Figure 3, the button "Fermer cette fenêtre"). Some other issues remained unsolved due to technical or logistical reasons: (1) the font size and symbols in the forum and video-player interfaces did not facilitate reading; (2) the post button for forum messages was at the bottom of the screen, requiring the use of the scrollbar; and (3) the least experienced participants often double clicked in the website, which was in conflict with the one-click activated "light box" effect, as the second click immediately closed the

window. For each of these problems, a clear explanation was provided in the user's manual.

Usability Test of v1.2

There were two additional problems that were identified during the second usability test. The website display varied according to the Internet browser and/or the computer model, and some participants did not know how to use the hyperlinks in the website. We adapted the Internet and printable version of the user's manual, taking into account the results of both usability tests, including the issues without a quick or easy solution (Table 2).

Additional Findings From the Usability Tests

Although during the usability tests the evaluators found most of the problems reported by users in the interviews, the evaluators also identified additional problems regarding the computer interface, and the Internet browsers. The mouse cursor and the scrollbar were not visible enough on the screen (lack of contrast or small size), and some participants did not distinguish the website settings from the Internet browser or

computer interface. For instance, a participant recommended changing the order of icons of the Internet browser because he thought that the latter was part of the website. When asked to go back to the "home page" of the website, another participant closed the browser window, then could not find, unaided, the icon of the Internet browser to continue the task. These problems were observed even for the people with more than one year of experience of Internet use.

Quantitative Results of Usability Tests

Behavioral Analysis of v1.1 and v1.2

There were two psychologists using an observation grid who analyzed the videos of usability tests sessions with The Observer TX. The three main variables analyzed are presented in Table 3: (1) the duration of the task, (2) the total of errors, and (3) requests for help during the evaluation. We observed an important reduction in completion time and the total of requests for help after the website improvements were made between the first and the second iteration. However, the overall number of errors remained similar in the two versions, possibly owing to unsolved usability problems.

Table 3. Total performance in five step usability test (for v1.1 and v1.2).

Usability tests	Mean task completion time, seconds	Total group errors (n*error) ^a	Total group requests for help (n*help) ^b
v1.1, n=16	1866.14	103 (15)	36 (6)
v1.2, n=15	1042.40	96 (15)	5 (4)

^a n*error, number of persons who made at least one error

^b n*help, number of persons who asked for help

Usability/Satisfaction Survey

As shown in Table 4, the two website versions yielded similar scores. Overall the participants' opinions of the website were positive. The lowest scores were for the system's "ease of use". A plausible explanation was that most of the participants

evaluated website ease of use for themselves, but not for other seniors. During the semistructured interviews, the most prominent argument was that the "other seniors" might be in poorer health and cognitive status than the participant himself. This suggests that this item reflects the participants' perception of older adults more than their experience using the website.

Table 4. Results of the usability/satisfaction 5 Likert questionnaire.

Satisfaction questionnaire items	Version 1.1 mean (SD)	Version 1.2 mean (SD)
Overall website evaluation	3.19 (0.54)	2.80 (0.68)
Easy-to-use	2.75 (0.68)	2.47 (1.06)
Pleasant to use	2.94 (0.68)	2.60 (0.63)
Website structure	3.31 (0.70)	3.13 (0.83)
Website layout	3.07 (0.70)	3.00 (0.76)
Website font	3.19 (1.05)	2.87 (1.06)
Website colors	3.19 (1.28)	3.67 (0.40)
Overall mean score	21.63 (2.90)	20.53 (3.40)

Discussion

Program Development

In this paper, we describe the iterative development of a Web-based psycho-educational program (Diapason) aiming to

reduce or prevent stress in caregivers of PWAD. To our knowledge, this is the first published work describing a user-centered design process for the development of a program addressed to caregivers of PWAD. To that end, we involved end-users and health care professionals in a double iterative design, allowing for a cyclic adaptation of the content and design

to the targeted population. During the whole process, our project team elaborated tailored guidelines for the engineer's mission, based on their own professional experience, but also taking into account the feedback from end users.

In fact, the involvement of end-users was decisive in the development of our program. The caregivers and healthy older adults pointed out various website usability deficiencies which had been unnoticed by the professionals. In agreement with the user-centered design approach, our aim was to prevent users lacking the necessary cognitive (experience or abilities) or physical resources from having to deal with the maladjusted and imposed technology devices [13]. Various authors have demonstrated the relevance of this approach to design eHealth interventions. For instance, Chiu and Eysenbach [11] found that caregivers attracted to a service which they considered useful, could eventually stop using it if they perceived the service as nonuser-friendly. Furthermore, focusing on caregivers' needs (and their representatives) during the development process is a critical aspect for the acceptability and adoption of interventions [6].

Principal Findings

The Proof of Concept evaluated the program's content and website usability, and was carried out with a group of caregivers of PWAD, consisting of children and spouses. As hypothesized by our team, and in accordance with the literature [13], the difficulties linked to usability issues were preeminent in older participants. Thus, the usability tests were focused on adapting the program in a senior-friendly website. As a consequence, we decided to privilege the recruitment of a group of healthy older persons rather than the (overwhelmed) caregivers for usability tests.

In order to obtain a more comprehensive appraisal of usability tests' results, we designed a mixed research method combining behavioral analysis with think aloud method, individual interviews, and questionnaires [13]. In this study, the questionnaire was the least sensitive and informative of the three methods. A plausible explanation is that closed-ended questions offer answers on "what" the users' opinions are, or "how" difficult the website is to use, but they do not give information as to "why" this might be. For example, researchers may obtain information on the degree of disagreement about an item, but not "why" the subject disagrees with it. In contrast, interviews and behavioral analysis (using thinking aloud) provided us with valuable and accurate data about the difficulties that users encountered in the website. For instance, additionally to usability issues described elsewhere, we observed that the participants confused the website and the Internet browser interfaces, and some had many difficulties with the computer interface or Internet browser themselves. As stated by Nielsen, even the most recent and popular operating systems Interfaces could present important usability issues, which entail cognitive overhead and add memory load [26]. Therefore, designers and evaluators of website usability should effectively disentangle website conception issues from problems due to computer and Internet environments (eg, Windows 8, Internet browser...).

It is also noteworthy that most of the older adults who filled out the satisfaction questionnaire during usability tests considered

the website easy-to-use for them, but not for other seniors. They argued that they thought about older adults with poorer health and more perceptual and cognitive deficits than themselves. This result matched those of previous studies by our team [27]. In both projects we explained to the participants (older adults) that the study aimed to identify their needs to create a senior-friendly technology. As described in this study, older adults rarely identified themselves as the "target" of gerontechnology, which was not intended for them, but for "other" older adults who may be (much) older, frailer, and more isolated than they are. This attitude may be due to "negative self-stereotyping", described in the literature [28,29]. In our study, children of PWAD (see in Proof of Concept section) also expressed this stereotyping of aging people. These results prove the advantage of observation methods, which provide an objective basis for the (un)necessary improvements.

As regards the program's content, the project team designed the Web-based Diapason program based on the Aide dans la Maladie d'Alzheimer (AIDMA) program content, retaining the most pertinent information and making it more accessible and easier to use. In fact, the AIDMA program was proposed in 2 hour face-to-face sessions, while we adapted the Web-based program to be used 15-20 minutes per week. Nevertheless, slight changes in topics were required through the development process, since some of them had already been tested by our team in the AIDMA project [17], and improved based on professionals' and caregivers' feedback.

Finally, although most of the professionals and end-users judged the Web-based program likely to be useful for isolated caregivers, some of them also worried that these interventions might increase (or reinforce) caregivers' isolation. We also encountered health care professionals who rule out the use of technologies and claim face-to-face interventions are the only way to help patients and their families. In our team, even if we recommend the use of face-to-face interventions, we also consider it appropriate to propose additional support for caregivers or for patients who cannot benefit from on-site psycho-educational programs.

Limitations and Lessons Learned

The acknowledged limitations of the present work might be useful for methodological and logistic considerations in future projects. First, even if our usability questionnaire was more adapted to our project context, it did not include items intended to measure "learnability" and "usefulness" perceptions [30], instead, we conducted the interviews at the end of the evaluations exploring these constructs. To improve the analysis of both dimensions, we recommend to conduct a field study during the development process, such as pilot tests in which the users have access to the program for one or two weeks [31]. In fact, these two measures would be valuable if some usability issues remained unsolved, as in our study. The difficulties encountered by the users may demand a learning process, and the developer has to know whether the website facilitates this process. Additionally, a pilot test may be a reassuring step before a clinical trial.

In this work, the involvement of both professionals and end-users was critical to develop a ready-to-use eHealth program

[13,14,32]. Moreover, this work provides additional arguments supporting the effectiveness of using usability guidelines to increase Internet accessibility for older adults [20]. Nonetheless, based on our current knowledge about website usability for seniors, we think that some ergonomic mistakes in the first versions of our website could have been prevented earlier in the development process, with the help of an expert in ergonomics at these stages. For instance, we recommend avoiding the use of open source “ready-to-use” programs, since they do not always respond to the universal design criteria.

Finally, and in accordance with other studies [20], our findings highlighted the relevance of using a mixed method approach, combining subjective and objective methods, such as observation analysis and interviews, to obtain complementary data.

Conclusions

The implementation of Web-based programs requires the adaptation of the system, including content and ergonomics, to match the needs of target populations. In fact, even when the content and aims are well established and tested, the face-to-face programs need to be reviewed and adapted for Internet use. Only the optimal usability and readability of interventions may prevent the underuse or incorrect use of these programs. Through usability iterative evaluations, the latest website version of our program has been improved, and is currently being tested in a randomized clinical trial [33]. For future user-centered design studies we recommend the following: (1) involving end-users from preconception stages, (2) using a mixed research method (mainly based on interviews and observations) in usability evaluations, and (3) implementing pilot studies to evaluate acceptability and feasibility before a clinical trial.

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Authors' Contributions

VCL managed, contributed to the design, implementation, and results analysis of the study, as well as edited the paper. FM contributed to the adaptation and rewriting of the program content, and moderated the project team workshops. JW participated in the data analysis and the editing of the paper. BB developed the latest versions of the website, fixed most of the usability issues, and edited the paper. MP contributed to the editing of the paper and the results analysis. JDR contributed to the adaptation of the program content and editing of the paper. IG contributed to the data analysis and editing of the paper. ASR is the main investigator, supervised the study, oversaw the implementation of the project, and edited the paper.

Conflicts of Interest

None declared.

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Abbreviations

AIDMA: Aide dans la Maladie d'Alzheimer

PWAD: people with Alzheimer's disease

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Original Paper

Enhancing Parental Motivation to Monitor African American Adolescents' Diabetes Care: Development and Beta Test of a Brief Computer-Delivered Intervention

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Abstract

Background: African American youth are at increased risk for poor diabetes management. Parenting behaviors such as parental monitoring are significant predictors of youth diabetes management and metabolic control, but no intervention has targeted parental monitoring of daily diabetes care.

Objective: The purpose of the present study was to develop and pilot test a three-session computer-delivered intervention to enhance parental motivation to monitor African American pre-adolescents' diabetes management.

Methods: The 3 Ms (Medication, Meter, and Meals) intervention was based on the Information-Motivation-Behavioral Skills (IMB) model of health behavior change and Motivational Interviewing approaches. Five caregivers of African American youth aged 10-13 years diagnosed with type 1 diabetes for a minimum of one year (ie, the target population) reviewed the intervention and provided feedback via semi-structured interviews. Interviews were transcribed and analyzed using thematic analysis.

Results: Caregivers' responses to interview questions suggest that The 3 Ms was helpful (minimum rating was 8 out of 10) and they would recommend the program to another parent of a child with diabetes (minimum rating was 9 out of 10). Three of five reported that The 3 Ms program increased the likelihood that they would talk to their child about diabetes. Thematic analysis suggested two primary themes: caregivers found the intervention to be a useful reminder of the importance of supervising their child's diabetes care and that it evoked a feeling of shared experience with other parents.

Conclusions: The 3 Ms computer-delivered intervention for increasing parental monitoring of African-American youth with type 1 diabetes was well-received and highly rated by a small sample of representative caregivers.

Trial Registration: ClinicalTrials.gov NCT01515930; <http://clinicaltrials.gov/ct2/show/NCT01515930> (Archived by WebCite at <http://www.webcitation.org/6Rm0vq9pn>).

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KEYWORDS

parenting; diabetes mellitus, Type 1; motivational interviewing; health behavior; intervention studies; African Americans; computer-assisted instruction

Introduction

Management of type 1 diabetes (T1D) is complex, demanding, and requires daily motivation and self-control [1]. Diabetes management declines during adolescence [2-6] due to both biological [7,8] and behavioral mechanisms [2,4,5,9]. This pattern often persists into adulthood [10-12] and is associated with the development of poor metabolic control [13-15], the onset of complications [16], and increased health care costs [17]. Although African American adolescents are more likely to experience problems with diabetes management [18] and increased metabolic control [18-20], few intervention studies have focused on this group.

Maintaining parental involvement in diabetes care promotes optimal diabetes management [21-24] and metabolic control [24,25]. However, parents commonly withdraw their involvement in diabetes care as youth enter adolescence [25-28], often solely as a function of age and not youths' capacity for autonomous self-care [21,23,29,30]. Recent studies have shown that parental monitoring of adolescents' daily diabetes care—that is, information-seeking about their child's diabetes care behaviors and direct supervision and oversight of those activities [31]—is a significant predictor of youth diabetes management and metabolic control [32-34]. At least one study has also found parental monitoring of adolescents' diabetes care to be lower among non-white caregivers [35]. While other parenting behaviors and family interactions have been targeted in order to maintain appropriate diabetes care in adolescents with T1D [36-38], parental monitoring of daily diabetes care—whether in general or specifically with African-American youth—has not previously been the focus of a targeted intervention.

Motivational Interviewing (MI) [39] is a client-centered, directive method for enhancing intrinsic motivation to change problem health behaviors by exploring and resolving ambivalence. MI evokes behavior change by increasing motivation and self-efficacy through altering key decisional and self-regulatory balances by eliciting “change talk” from participants. Change talk, participants' statements about their own desire, ability, reasons, need for, or commitment to change [40], is linked to actual behavior change [41]. MI has been widely adapted for the treatment of several health conditions including obesity [42], poor dietary practices [43], and poor diabetes management [44] in both adolescent and adult populations [45,46]. Recently, MI has been also used as a brief intervention to increase parental monitoring in populations of young children at risk for behavioral difficulties [47-49]. Additionally, MI has been successfully utilized with diverse populations in the United States and around the world with at least one meta-analysis suggesting stronger effects among minorities [46].

Despite the evidence supporting the use of MI to address poor parental monitoring of diabetes care, its integration into clinical practice is hindered by several factors. Integrating intervention

programs, even brief ones, into medical practice presents significant time, financial, and logistic obstacles [50,51]. In addition, training clinicians to effectively deliver brief behavioral interventions, including MI, with a high degree of treatment fidelity is resource intensive [52-54]. On the other hand, computer-delivered interventions, once developed, hold the potential to be more easily streamlined into routine diabetes clinic visits. For example, medical assistants or other paraprofessionals who interact with patients during clinic visits could be trained to orient and log patients on to a tablet computer, which could then deliver the intervention while patients are waiting to be seen. Two recent studies have demonstrated success using laptop/tablet computers to deliver computer-based interventions in both the outpatient clinic [55] and inpatient settings [56]. In addition, integrating a behavioral intervention into routine clinical care may safeguard against common pitfalls suffered by many such interventions, including computer-delivered interventions. For example, attrition may be minimized by reducing the participation burden on the participant (ie, they do not have to make a separate trip or find time to log on to a Web-based application during a regular day) and capitalizing on a time when patients are present but unengaged (ie, they are waiting to receive their medical care).

There is growing literature supporting the use of computer-based formats to deliver brief interventions such as MI. Computer-delivered interventions offer several other advantages over traditional face-to-face interventions. The anonymity inherent in delivering an intervention by computer is associated with increased disclosure of information perceived to be sensitive [57], potentially increasing its acceptability. Computer-delivered interventions are easily replicated across persons and settings with a high degree of fidelity. Programming permits the translation of the intervention to any language and literacy level as well as individualized tailoring, a critical component of effective computerized interventions [58]. Brief, computer-delivered interventions can be widely disseminated, in this instance, delivered opportunistically (ie, during routine clinic visits) to all or most individuals, eliminating the need to screen individuals or target members of a high risk group. Broad dissemination increases an intervention's population impact, that is, the effect of the intervention when considered across the entire population of affected individuals, even if the intervention effect is relatively small [59,60]. Although within the context of diabetes self-management, small effects are linked to significant health improvement. The Diabetes Control and Complications Trial [16] demonstrated that as little as a 10% reduction in glycated hemoglobin (HbA_{1c}) decreases the risk of complications by approximately 40%. Two recent reviews suggest computer-delivered interventions have small effects on diabetes self-management in adults with type 2 diabetes [61,62]. Together, this research provides compelling evidence to support brief, targeted interventions for diabetes.

The present study sought to develop and pilot test a brief, computer-delivered intervention targeting parental motivation

to monitor pre-adolescents' diabetes management. The intervention targeted caregivers of urban, African American pre-adolescents aged 10-13 years—youth who are beginning to assume greater responsibility for diabetes self-care and, therefore, are at increased risk for parental disengagement from diabetes care [23,63]. The newly developed intervention was a three-session, avatar-delivered, interactive program called *The 3 Ms*, which refer to the key diabetes self-care behaviors—Medication, Glucose Meter, and Meals.

Methods

Intervention Development

Intervention development followed the Information-Motivation-Behavioral Skills (IMB) model of health behavior change [64] and utilized approaches consistent with MI [65,66]. The IMB model posits that behavior change results from the joint function of three critical components: (1) accurate information about risk behaviors (eg, risks of letting adolescents complete diabetes care in the absence of parental monitoring) or their replacement health behaviors (eg, benefits of daily parental monitoring), (2) motivation to change behavior, and (3) behavioral skills necessary to perform the behavior (eg, self-efficacy) [64]. Thus, the goal of the intervention was to improve parental monitoring of daily diabetes care by increasing parents' knowledge of, motivation for, and confidence in parental monitoring. The intervention was developed with the intention that it be delivered during three consecutive routine diabetes clinic appointments by clinic staff. For practices, like the study site, that adhere to the American Diabetes Association's clinical recommendations for frequency of medical care for youth with T1D [67], the intervention sessions would be delivered at 3 to 4 month intervals.

The behavioral targets were based on three recommendations, which were termed The 3 Ms: (1) Watch your child give as many doses of insulin each day as possible (Medicine), (2) Check your child's blood glucose meter at least once a day (Meter), and (3) Eat at least one meal each day with your child (Meals). The name The 3 Ms was chosen to function as a mnemonic to increase the likelihood that caregivers would recall these three key behaviors after the conclusion of the intervention. Figure 1 illustrates the various pathways through which participants could progress through the intervention.

To enhance caregivers' knowledge of the importance of parental monitoring, an actor portraying a physician in a video clip delivered a small amount of psychoeducation at the beginning of Session 1 (Component 1.1). The goal of providing this information was to educate the participant about the recommended behavior change (ie, what parental monitoring is), its key features (ie, what behaviors constitute parental monitoring), and its benefits (ie, how daily parental monitoring of diabetes care is related to improved diabetes management and diabetes health). This psychoeducation was reinforced using a brief peer testimonial video clip in which an actor portraying a parent of a child with diabetes described her (fictional) experience with increasing parental monitoring of daily diabetes care. In this video clip, the parent describes how she came to learn of her child's suboptimal diabetes care behavior and the

resulting decline in his health status. She then recounts how increasing her parental monitoring led to improved diabetes care and several associated behavioral changes, eg, increased school performance. Providing such information is consistent with the IMB model, which suggests motivational approaches are most effective in the context of sensitively provided information about a health-related behavior [68]. In order to increase cultural competency, the scripts for both video clips were reviewed and tailored for appropriate language, communication style, and content by a pediatric health behavior researcher with expertise in developing interventions for urban, minority adolescents, specifically African American adolescents. In addition, the actors selected for the roles in the video clip were African American.

After educating participants about parental monitoring and its potential benefits, all participants were asked to rate the importance of implementing The 3 Ms using an adapted version of the Rollnick Readiness Ruler [69] (Component 1.2). Participants' perceptions of the importance of implementing The 3 Ms determined which one of two distinct treatment components they received. Participants reporting low importance for parental monitoring were directed through exercises to explore their ambivalence and/or low motivation for increasing their parental monitoring behavior (Component 1.3). Participants reporting high importance for parental monitoring completed activities designed to reinforce their belief in the value of monitoring (Component 1.4).

Both groups were then directed to a ruler assessing their confidence in implementing The 3 Ms (Component 1.5). Those with low confidence were branched to activities designed to build confidence in implementing The 3 Ms (Component 1.6) and those with high confidence were reinforced (Component 1.7). All participants ended the session with a goal-setting component where participants were given the option of choosing three goals: "use The 3 Ms", "try other strategies to support their child's diabetes care", or "think about it" (Component 1.8). They recorded their goal on a goal-setting worksheet provided by study staff who made a single photocopy that was mailed to the participant approximately two months later. Session 1 required approximately 15-20 minutes to complete.

At their next diabetes clinic visit (approximately 3 to 4 months later), participants began Session 2 by selecting the parental monitoring goal they had worked on since Session 1. Participants who reported their goal was "use The 3 Ms" (Component 2.1) or "try other strategies to support their child's diabetes care" (Component 2.2) were then asked to describe their experience implementing that goal. Those reporting positive progress toward their goal were directed to activities designed to reinforce their success and bolster their confidence (Component 2.4). Those less positive about their progress were branched to exercises designed to explore the barriers they might have encountered and bolster their confidence to continue trying to implement their goal (Component 2.5). Both groups ended the session with the goal-setting component (2.10).

Participants whose reported goal was to "think about" parental monitoring (Component 2.3) were directed to an importance reassessment (Component 2.6) to gauge their current readiness

to change. Participants who indicated that parental monitoring was not important received an autonomy-supportive message acknowledging that the decision to monitor was their own and encouraging them to continue to think about it (Component 2.7). Those reporting low or high importance for monitoring were branched to motivation-enhancing exercises tailored to their specific level of readiness. Those with low motivation were directed to exercises designed to explore their ambivalence for increasing their parental monitoring behavior (Component 2.8), whereas those with high importance completed activities reinforcing their reasons for monitoring (Component 2.9). Both groups were then directed to the goal session component (2.10). Session 2 required approximately 12-15 minutes to complete.

Session 3 was a re-administration of Session 2 and was completed approximately 3 to 4 months after completing Session 2 (ie, at their next diabetes clinic visit). Participants again identified the parental monitoring goal they had been working on since their last session and proceeded through the intervention session as described above. Session 3 ended with a motivational message encouraging the caregiver to communicate with their health care team should they have questions in the future.

Sessions were delivered by an animated character, or avatar, that has previously been used successfully (received high satisfaction ratings) with African American populations (see

Figure 2)[55,56,70,71]. The avatar’s communication style and demeanor were consistent with principles of MI, suggesting that factors such as empathy, optimism, and congruence are strongly related to more client behavior change [72]. Previous research has demonstrated that computer avatars can successfully use these relational skills [73]. Significant efforts were made to ensure that the avatar delivered The 3 Ms with high MI fidelity. For example, throughout the intervention, the avatar reflected back the participant responses with affirmations to boost self-efficacy and statements emphasizing personal choice. As depicted in Figure 1, participants’ intervention trajectories were tailored based on their responses to importance and confidence assessments and the avatar’s communication was scripted within each trajectory to be consistent with the participants’ current readiness to change.

Once developed, the intervention was reviewed by two experts. A pediatric diabetologist (KM) reviewed recommendations in The 3 Ms for consistency with the treating health care center’s diabetes treatment guidelines as well as the recommendations of the American Diabetes Association [67]. CJ, a pediatric health behavior researcher with expertise in developing interventions for urban, minority adolescents, also reviewed the complete intervention to improve its cultural appropriateness. These reviews resulted in minor edits to the content and language of the sessions.

Figure 1. Flow chart of The 3 Ms Intervention.

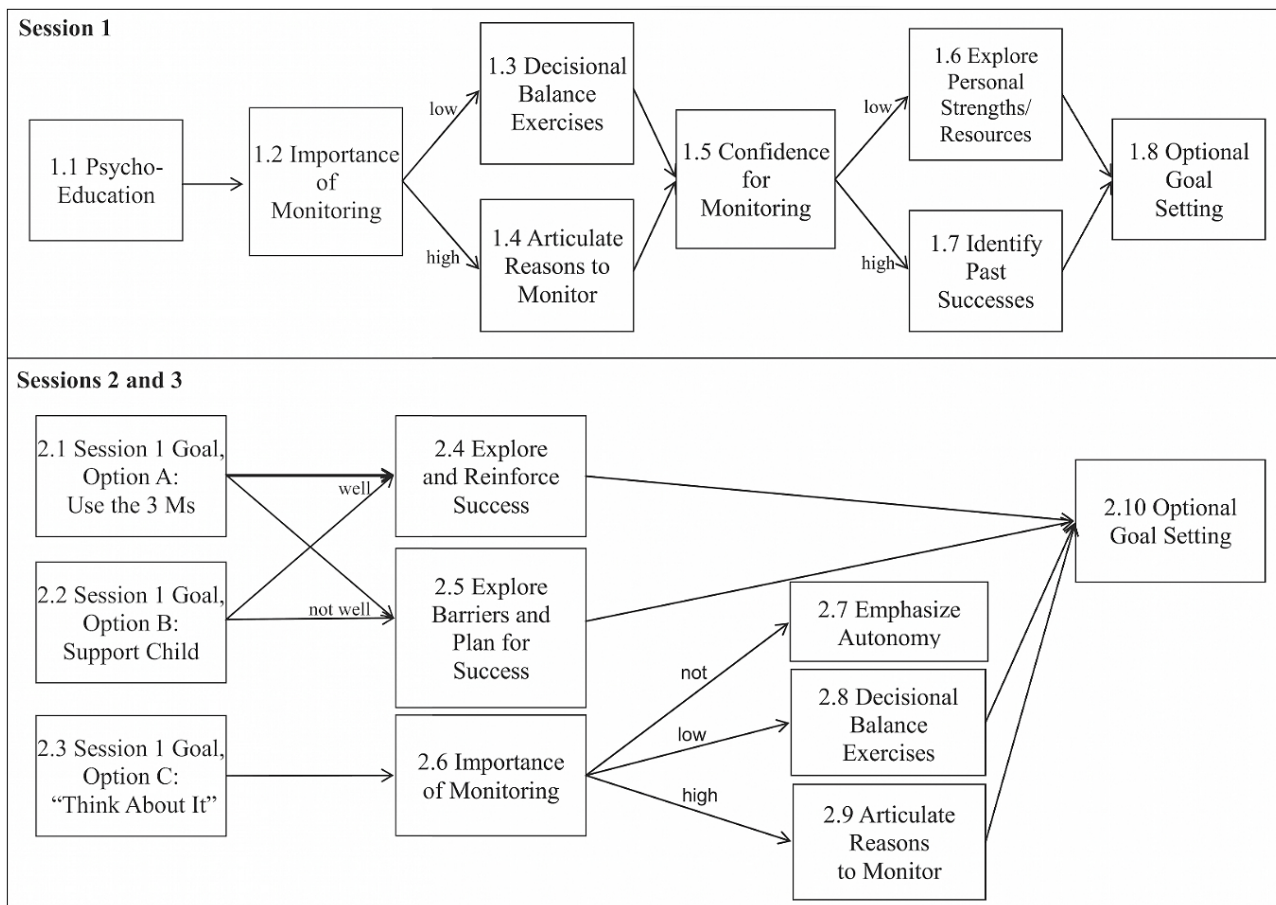
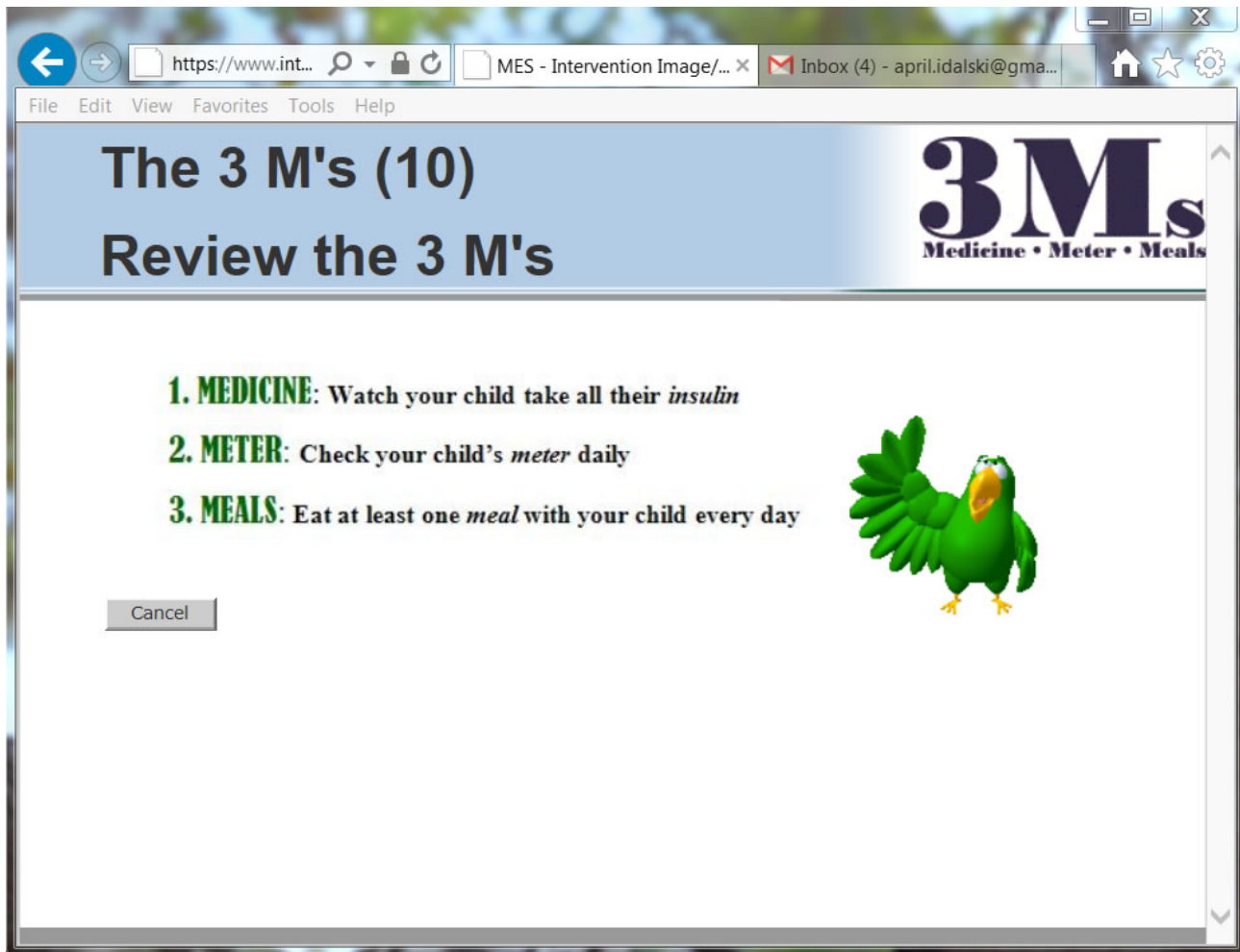


Figure 2. Screenshot of The 3 Ms Intervention.



Beta Test

The primary caregivers of five African American youth aged 10-13 years diagnosed with T1D for a minimum of one year (ie, the target population for the intervention) were recruited from a large, urban teaching hospital located in a large Midwestern city using convenience sampling procedures. Primary caregiver was defined as the person who lived with

and helped the child with his/her diabetes care most of the time. Table 1 describes the sample characteristics. The diabetes clinic staff mailed letters of introduction to all eligible families. Disinterested families could opt-out of any further contact. Research staff followed up with the remaining families to assess their interest in participation. The research protocol was approved by the university's Institutional Research Board. All caregivers provided informed consent to participate.

Table 1. Participant characteristics.

Participant number	Caregiver gender	Child age (years)	Child gender	Illness duration (years)
1	Female	12.4	Female	4.0
2	Female	12.2	Female	2.4
3	Female	11.5	Female	2.7
4	Female	11.6	Male	2.0
5	Female	11.0	Male	5.8

Participants' Ratings of The 3 Ms

Caregivers participated in one research visit at the research offices. During this visit, they first reviewed the intervention as if they were a participant, and then completed a semi-structured individual interview designed to elicit their feedback on the intervention's appropriateness, utility, and cultural relevance. Interview questions were both closed-ended

(“On a scale of 1 to 10, with 1 being not at all helpful and 10 being extremely helpful, how helpful do you think the computer program will be in helping the caregivers of children with diabetes identify ways to better supervise their child’s diabetes care?”) and open-ended (“If you could change any part of the program, what would you change?”). Caregivers received a US\$25 gift card to a major retailer for completing the study.

Thematic Analysis

In preparation for analysis, the interviews were transcribed by a professional transcription service. The transcribed interview data were analyzed using thematic analysis conducted in NVivo 9, a qualitative data analysis software package [74]. Responses to closed-ended questions were tallied (see Table 2). Two coders, one being the primary author and the second a research assistant, independently coded responses to the open-ended questions using the procedure outlined by Aronson [75] with additional guidance from Braun [76]. First, coders reviewed each transcript identifying responses to each interview question. These initial themes corresponded to the broad areas of interest the interview was designed to assess. They included participants' perceptions of the helpfulness of the intervention, enjoyable intervention components, key intervention components, intervention acceptability, intervention's impact on diabetes, and preference for motivational versus directive physician psychoeducation. Coders coded transcripts independently, then

met to compare their coded transcripts before proceeding. Coding discrepancies were discussed and resolved; the consensus coded transcript was used for the subsequent coding pass. In the second coding pass, caregivers' responses to each question were examined to identify commonalities, or themes. Using the caregivers' own words, these themes were labeled, described, and applied to all the data, across all interview questions. Coders again coded independently, met to compare their coded transcripts, and reconciled coding discrepancies. Throughout this process, the theme descriptions were continuously augmented and clarified to ensure that all participants' experiences were represented. The final result of this work was four themes, described more fully in the results below. Two themes described aspects of the structure and delivery of the intervention, the avatar, and The 3 Ms mnemonic that participants particularly enjoyed. Two themes pertained to the intervention's relevance and utility, the importance of supervision, and shared experience.

Table 2. Caregiver ratings of The 3 Ms intervention.

Participant number	Helpfulness rating ^a	Recommendation rating ^b	Increased likelihood of talking to child about diabetes?	Physician video preference (Directive vs Motivational)
1	8	9	No	Directive
2	10	10	Yes	Motivational
3	9	10	Yes	Directive
4	10	10	Yes	Directive
5	10	10	No	Directive

^aAnchored with 1 corresponding to "not at all helpful" and 10 to "extremely helpful".

^bAnchored with 1 corresponding to "not at all" and 10 is "definitely".

Results

Participants' Ratings of The 3 Ms

Table 2 presents caregivers' responses to the closed-ended questions. All caregivers rated the helpfulness of The 3 Ms in helping caregivers identify ways to better supervise their child's diabetes care at least an 8 out of 10, where 10 corresponded to a perception that the intervention was "extremely helpful". Four caregivers rated their likelihood of recommending The 3 Ms program a 10, meaning that they would "definitely" recommend The 3 Ms to another parent of a child with diabetes. Three caregivers reported that The 3 Ms program changed the overall likelihood that they would talk to their child about diabetes, whereas two caregivers reported that they already engaged in regular conversations about diabetes care and related topics with their child.

Thematic Analysis

Thematic analysis of caregivers' responses to the open-ended questions identified two themes regarding the structure and delivery of the program. All five caregivers reported that the use of an animated avatar to deliver the intervention increased their enjoyment of the program: "The little avatar made it exciting, not seem so boring"; "That was cute. It made it interesting." In addition, four of the five caregivers mentioned the intervention mnemonic (The 3 Ms) in their interviews.

Caregivers found the mnemonic to be useful for remembering key monitoring behaviors, "something that you can remember", and simple enough to be easily implemented, "The 3 Ms are something that you can keep up with."

In addition, two broad themes related to the intervention's relevance and utility were identified.

Importance of Supervision

All the caregivers who reviewed the intervention found it to be a useful reminder regarding the importance of supervising their child's diabetes care. Specifically, caregivers remarked that it was helpful to be reminded that even "good" children—those demonstrating independence and responsibility—need to be supervised. Caregivers perceived the intervention to be useful because parents often reduce their supervising behavior over time as they fall into routines, become lax or frustrated, or otherwise fatigued.

You do learn that, no matter how responsible you think your child is, they're not as responsible as you really think they are, and you really do need to check and monitor behind them. Not because they're bad children, just, you know, they're children.

I'm always on my daughter about, you know, thinking that she's doing it and then she's not or she's saying she is and, you know. Now I realize it is hard for them

when they get to a certain stage or age to maintain. And I'm just taking for granted that she's doing it.

So, I mean, it's kind of a reminder and kind of a wakeup call in the same sense, you know. We still need to, even though they're getting older, we still need to monitor what's going on. Because we all get comfortable with thinking that we're doing the right things and, even though we could be, but sometimes I'm sure we all fall short on checking the meter or not because the kid said, "I did it".

Shared Experience

All five caregivers reported the peer testimonial provided them with a feeling of having a shared experience. Specifically, they reported hearing the perspective of another parent who thought her child was independently and responsibly managing diabetes only to learn that the child was not doing as well as she thought was extremely helpful. This experience provided them with a sense that "I'm not alone" and that other parents of young adolescents with chronic illnesses struggle with these issues too.

Her daughter seemed similar to mine, you know. My child caught on very fast, way quicker than I did. Before she got released from the hospital, she knew how to give shots, blood sugar. The doctors and everyone made sure we were prepared when we got home. And so, her situation seemed similar that, because my child learned it so soon, I thought she was ready to take more responsibility towards her diabetes, and found out, like that mom, that my child wasn't as responsible as I thought she was. So, it was helpful to see that somebody else was going, to hear, rather, and see that someone else was going through the same things. So, letting parents know you're not alone out there. Your child is not the only one. There's nothing wrong with your child.

While feedback was positive overall, caregivers did raise one concern with the intervention. Two caregivers suggested that The 3 Ms might be most appropriate for caregivers of newly diagnosed children. Specifically, they indicated that "after so many years, you've heard all of this from the doctors". One of the two did acquiesce that "it's still helpful to hear some of the things Dr. Moore (the actor portraying a physician in the video) said". A third caregiver suggested that The 3 Ms was a useful "refresher" after having been diagnosed for many years:

I think it's pretty good though because the only other program or training or what to do type of thing was at the beginning when she was diagnosed, when they give the classes and things like that. So, I mean, coming back years later, and even though you have your hospital visit and clinic visits and stuff like that, it's still different to be able to, I guess a refresher type thing.

Finally, caregivers were also asked to review two versions of the physician psychoeducation video clip. In one video, the physician's speech was scripted to be consistent with the principles of MI. To illustrate, autonomous decision making

was emphasized at several points. For example, in her initial comments, the physician acknowledges that "How you parent your teen with diabetes is up to you and your family" and "you can decide for yourself just how important it is to be involved in your teen's diabetes care as your teen gets older". Later, when making her recommendation, she encouraged parents to monitor daily, but explained that it was their choice whether they changed their monitoring behavior, "So, those are the facts. What you do with them is up to you." Also consistent with MI, before providing the caregiver with information about parental monitoring, the physician asks permission to give that information, albeit indirectly, "I hope you won't mind if I take just a minute to tell you a little about parenting a teen with diabetes".

In contrast, the other physician video was more directive; in this version, she stated clearly and firmly that that it was in a parent's best interests to monitor their child's diabetes care daily: "As a doctor, I must tell you that it is very important for you to supervise your child's diabetes care every day". Her initial comments and recommendations for monitoring were similarly presented in a very direct manner emphasizing the physician's expertise and authority in this area, "As a doctor, I must tell you that it is very important for you to supervise your child's diabetes care every day" and "the best advice I can give you is to start daily supervision as soon as possible". This approach is consistent with the "Advise to Quit" recommendation of the "5 As" smoking cessation intervention, a brief clinical intervention grounded in empirical support and expert opinion that states, "In a clear, strong, and personalized manner, urge every tobacco user to quit" [77].

The videos were presented in alternating order to consecutive participants. Four caregivers preferred the directive video over the motivational video. When asked to explain their preference, caregivers stated that the directive video conveyed a greater sense that parental monitoring was important and contained more information (despite both videos containing exactly the same informational content). Caregivers also indicated a directive approach was appropriate for discussions of children's health: "I think sometimes you just don't need to always sugarcoat things. You just need to tell it how it is, because it's a very serious disease and you can die from it."

Discussion

Principal Findings

The results of this study suggest that The 3 Ms is an appropriate and acceptable intervention for caregivers of children with T1D. Caregivers provided positive feedback via both quantitative ratings and qualitative comments. Caregiver comments suggested that the intervention was both helpful and enjoyable.

This study provided insight into caregivers' preferences for receiving psychoeducation related to their children's health delivered by a computer-based intervention using a motivation-enhancing framework. Although MI theory suggests that behavior change information is best received under conditions where individuals' autonomous decision making is supported [66], four of the five caregivers in this study preferred

a directive approach over a motivation-enhancing approach for the information about the importance of parental monitoring presented in video clips. One interpretation of this finding, supported by caregivers' comments, is that motivational approaches may be preferred when discussing one's own behavior or health, but when discussing a child's health, caregivers prefer a directive approach. The participants in this study preferred a directive approach, a preference that will be honored in the pilot study; however, more research is needed to empirically test whether a directive approach is more effective at evoking behavior change than motivational approaches in this context.

To increase the cultural competency of the intervention, a deliberate effort was made to select actors to portray the physician in the psychoeducational video clip and the caregiver in the peer testimonial with whom the target population would identify, that is, African American actors. Although participants were not directly asked about their ability to relate to the physician and caregiver portrayed in the video clips, a primary theme, Shared Experience, emerged from the qualitative analysis indicating that video clips did evoke such feelings. A meta-analysis examining the effect of culturally adapted interventions (interventions designed for a specific cultural group) found that culturally tailored intervention were four times more effective than interventions that were not culturally tailored [78]. Additional research is needed to form a conclusion about the effect of the cultural tailoring of The 3 Ms intervention on participant outcomes.

Limitations

This study is limited by a small sample size. However, the sample size is justified by a need for small scale intervention development studies to develop and preliminarily validate interventions prior to resource-intensive randomized controlled trials [79]. A second limitation is the feasibility and acceptability of integrating a computerized intervention into routine diabetes clinical practice. Although at least two previous studies have reported successful testing of computer-delivered interventions

into outpatient [55] and inpatient medical settings [80], studies examining the implementation of a such an intervention using typical clinical support staff (ie, not research staff) is needed.

Future Steps

The next step of this research, currently under way, is a pilot randomized controlled trial to examine the ability of The 3 Ms to influence health outcomes in this high risk population. The pilot study is utilizing a randomized, repeated measures design where participants are allocated to one of three intervention arms. In Arm 1, 30 caregivers will receive the motivation-enhancing intervention targeting parental monitoring of their child's daily diabetes care described here and their children will receive a similar intervention targeting children's own daily diabetes care. In Arm 2, 30 caregivers will receive the motivation-enhancing intervention but their children will receive an attention-control intervention, three computer-delivered sessions of similar duration that provide diabetes education unrelated to parental monitoring or daily diabetes care. The educational topics are diabetes-related emergency preparedness, traveling with diabetes, and smoking and diabetes. In Arm 3, 30 caregivers and their children will both receive the control intervention.

Pilot study participants will be recruited from an urban, Midwestern medical center serving a patient population with a significant representation of ethnic minorities and families of lower socioeconomic status. Participants will complete four study visits; the first three will include both study-related assessments as well as the delivery of the interventions and the fourth will be a follow-up assessment only. The primary outcomes will be caregiver motivation for parental monitoring of daily diabetes care and adherence to the diabetes care regimen. Secondary outcomes will include parental monitoring behavior and glycemic control (hemoglobin A1c). At the writing of this report, recruitment into the pilot study was well under way; 67 participants were enrolled and randomized. Thus far, 91% of participants have been successfully retained across intervention arms.

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Conflicts of Interest

Steven J Ondersma is part owner of a company that markets the computer-delivered intervention authoring tool used to develop the intervention for this study. There are no other conflicts of interest.

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Abbreviations

IMB: Information-Motivation-Behavioral

MI: motivational interviewing

T1D: type 1 diabetes

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Protocol

Improving the Prevention of Cardiovascular Disease in Primary Health Care: The Model for Prevention Study Protocol

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Abstract

Background: Cardiovascular disease (CVD) is the leading cause of death globally, and accounted for nearly 31% of all deaths in Australia in 2011. The primary health care sector is at the frontline for addressing CVD, however, an evidence-to-practice gap exists in CVD risk assessment and management. General practice plays a key role in CVD risk assessment and management, but this sector cannot provide ongoing lifestyle change support in isolation. Community-based lifestyle modification services and programs provided outside the general practice setting have a key role in supporting and sustaining health behavior change. Fostering linkages between the health sector and community-based lifestyle services, and creating sustainable systems that support these sectors is important.

Objective: The objective of the study Model for Prevention (MoFoP) is to take a case study approach to examine a CVD risk reduction intervention in primary health care, with the aim of identifying the key elements required for an effective and sustainable approach to coordinate CVD risk reduction across the health and community sectors. These elements will be used to consider a new systems-based model for the prevention of CVD that informs future practice.

Methods: The MoFoP study will use a mixed methods approach, comprising two complementary research elements: (1) a case study, and (2) a pre/post quasi-experimental design. The case study will consider the organizations and systems involved in a CVD risk reduction intervention as a single case. The pre/post experimental design will be used for HeartLink, the intervention being tested, where a single cohort of patients between 45 and 74 years of age (or between 35 and 74 years of age if Aboriginal or Torres Strait Islander) considered to be at high risk for a CVD event will be recruited through general practice, provided with enhanced usual care and additional health behavior change support. A range of quantitative and qualitative data will be collected. This will include individual health and well being data collected at baseline and again at 12 months for HeartLink participants, and systems related data collected over the period of the intervention to inform the case study.

Results: The intervention is currently underway, with results expected in late 2015.

Conclusions: Gaining a better understanding of CVD prevention in primary health care requires a research approach that can capture and express its complexity. The MoFoP study aims to identify the key elements for effective CVD prevention across the health and community sectors, and to develop a model to better inform policy and practice in this key health priority area for Australia.

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KEYWORDS

cardiovascular disease; primary prevention; cardiovascular absolute risk; models; primary health care; mixed methods; case study

Introduction

Cardiovascular Disease in Australia

Cardiovascular disease (CVD) is the leading cause of death globally, and accounted for nearly 31% of all deaths in Australia in 2011 [1]. CVD accounted for the greatest spending at 12% (\$7.6 billion) of all allocated health care expenditure in 2008-2009 [2]. Addressing lifestyle risk factors (eg, physical activity, diet, and smoking) can reduce the risk of premature mortality by 66% [3]. The use of a cardiovascular absolute risk (CVAR) approach to the primary prevention of CVD, rather than the traditional single risk factor focus, is now well established and is a recommended approach to practice in Australia [4]. Despite the evidence base and demonstrated cost effectiveness of a CVAR approach, application of this method for identification and management of CVD risk is not the usual practice in Australia [5].

Cardiovascular Disease Prevention in Primary Health Care

Primary health care is at the frontline for the delivery of services that identify, prevent, and manage CVD risk. General practice plays a key role; however, this sector alone cannot provide the ongoing behavior change support that is often required for people at elevated CVD risk. Community-based lifestyle modification services and programs provided outside the general practice setting can have an important role in supporting and sustaining health behavior change. Fostering linkages between the health sector and community-based lifestyle services has been shown to improve population prevention outcomes [6].

The advent in 2011 of Medicare Locals, Australia's primary health care organizations, is particularly relevant to efforts to improve CVD prevention. Given their role of operationalizing the government's primary health care improvement program, the Medicare Locals are key agents in supporting the primary health care sector by undertaking chronic disease prevention and management activities [7]. The development of the general practice workforce via incentives to employ practice nurses and funding for the community sector to deliver community-based lifestyle modification programs is also significant [8,9]. These initiatives, along with the Medicare Locals, have the potential to increase the general practice and community sector capacity to support improved CVD prevention.

The Chronic Care Model

To support the development of chronic disease prevention and management systems, and to improve practice and enhance the collaboration between sectors, a number of models and frameworks have been used. Such models can act to communicate a vision to different stakeholders, prompt dialogue between groups, and help to define goals and objectives for activities [10]. In the area of chronic disease prevention and management, specific models have been used successfully to inform and evaluate activities. The Chronic Care Model (CCM)

has been central to chronic disease policy and practice globally since the late 1990s, and has been successful in driving quality improvement in chronic disease management [11]. Studies using the CCM as an implementation framework have consistently argued that system and patient level outcomes can be achieved by the implementation of the CCM, or even just some of its elements [12].

In 2001, Glasgow et al identified the potential for the CCM to be applied to the prevention of chronic disease [13]. They noted the many activities applicable to both chronic disease prevention and management, and identified that both require a proactive and system-oriented approach. The Expanded Chronic Care Model (ECCM) developed by Barr et al [14], combines the CCM with the action areas of the Ottawa Charter, a well known framework for health promotion [15]. Both the CCM and the ECCM have been identified as having the potential to inform improved CVD prevention practice [16,17]. However, the best model to improve practice in CVD prevention in primary health care is yet to be determined.

The Model for Prevention (MoFoP) study aims to build on the CCM and related models, identifying the key elements of a new systems-based model for the prevention of CVD that informs best practice.

The Model for Prevention Study

The MoFoP study aims to investigate a whole-of-system approach to the prevention of CVD in the primary health care setting. The MoFoP study will examine the *HeartLink* CVD risk reduction intervention in primary health care. The study will identify key elements of improved CVD prevention practice across the health and community sectors.

The aims of the MoFoP study are to: (1) test the feasibility of the *HeartLink* pilot processes including organizational readiness and resource implications for each key stakeholder group with regards to the implementation of the intervention; (2) measure the efficacy of the *HeartLink* pilot in six general practices in the Australian Capital Territory (ACT), Australia; and (3) identify the key elements of an effective model for the prevention of CVD in primary health care, and critical success factors for implementation and sustainability.

A mix of interrelating theoretical and framing approaches governing different aspects of the study have guided the study. For example, the trans-theoretical model of behavior (stages of change) informs individual behavior change [18], the normalization process theory relates to the implementation of the intervention [19], with the expanded chronic care model and complex adaptive systems approach providing overarching frameworks [14,20].

Methods

Study Design

The Two Research Elements

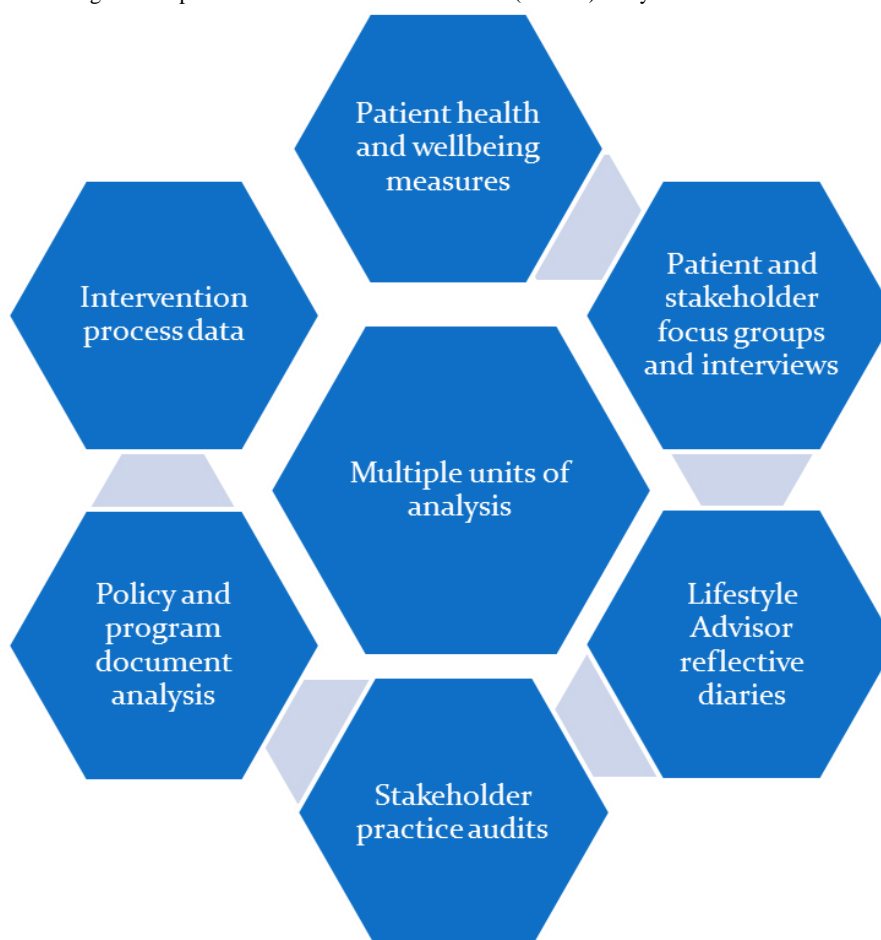
The MoFoP study will use a mixed methods approach to evaluate the *HeartLink* pilot, comprising two complementary research elements: (1) a case study, and (2) a one-group pre/post quasi-experimental design acting as a pilot for a proposed larger cluster randomized trial. The study design was informed by the mixed design approach used by Provost et al [21].

Case Study

We will use an embedded single case study design as described by Yin [22]. Yin defines a case study as an empirical inquiry

that, “investigates a contemporary phenomenon within its real-life context; when the boundaries between the phenomenon and context are not clearly evident, and in which multiple sources of evidence are used”, and where case study data is collected to test preidentified theoretical propositions. The study will consider the organizations and systems involved in the *HeartLink* intervention as a single case, with a number of aspects being examined as separate units of analysis within the case. Figure 1 illustrates this idea. This strategy will use quantitative and qualitative methods, and will consider a range of measures. The outcome of this descriptive case study will be a narrative of the case.

Figure 1. Units of analysis forming the components of the Model for Prevention (MoFoP) study.



One-Group Pre/Post Quasi-Experimental Design

The second component, the *HeartLink* intervention, uses a preexperimental, one group pre/post test design. A single cohort of patients 45-74 years old (or 35-74 years old if Aboriginal and/or Torres Strait Islander) considered to be at high risk for a CVD event within the next five years will be recruited through general practices, and provided with enhanced usual care and additional health behavior change support. CVAR for each patient will be determined using the Australian adaption of the Framingham based CVD risk score, with high risk being defined as a CVAR > 15% over the next 5 years [4].

The design has been informed by interventions in Australia and the United Kingdom, which also aimed to achieve CVD risk reduction through enhanced risk identification and reduction programs in primary health care [23-25]. *HeartLink* will use the ECCM as a framework to create improved prevention pathways in the primary health care sector, including providers of lifestyle modification services and programs outside the traditional health sector.

HeartLink Practice Recruitment

HeartLink is set in the ACT, Australia, and is a pilot intervention in six general practices, which have been selected to broadly

represent of the socioeconomic and demographic population in the region.

The practices that are recruited will be required to meet a number of inclusion criteria, including: (1) agreement that the patient has no additional payment to make from participation in the first recall visit and the 12 month follow-up visit, (2) agreement to have at least one practice nurse on staff to support the intervention, and (3) have the PEN Computer Systems Pty (Sydney, Australia) Clinical Audit Tool software.

HeartLink Patient Sampling Strategy and Sample Size

The patient sample size for the *HeartLink* intervention was determined by an examination of similar pilot studies [25]. However, resource constraints and the desire to minimize the burden on participating practices determined the final pilot sample size of 30 patients in each of the six practices, a sample of 180 in total. Due to the variability in practice population sizes, potential losses due to poor recall response, and failure to join or complete the intervention, which could be as high as 80% of the eligible registered patients in some practices (this is estimated from pilot work on practice data download and CVAR calculation), the aim is to recall as many patients with a CVAR > 15% as possible, within the six month recruitment period. A high dropout rate is expected due to the number of steps involved in moving from patient identification, to recall and recruitment, and finally to program participation and completion. This sample size should provide estimates of key parameters, such as possible effect size for the change in CVAR for patients, so that the optimal design of a full evaluation trial can be determined (see data analysis).

HeartLink Participant Eligibility and Recruitment

Inclusion and exclusion criteria for *HeartLink* were established. Patients needed to be 45-74 years old (35-74 years old for

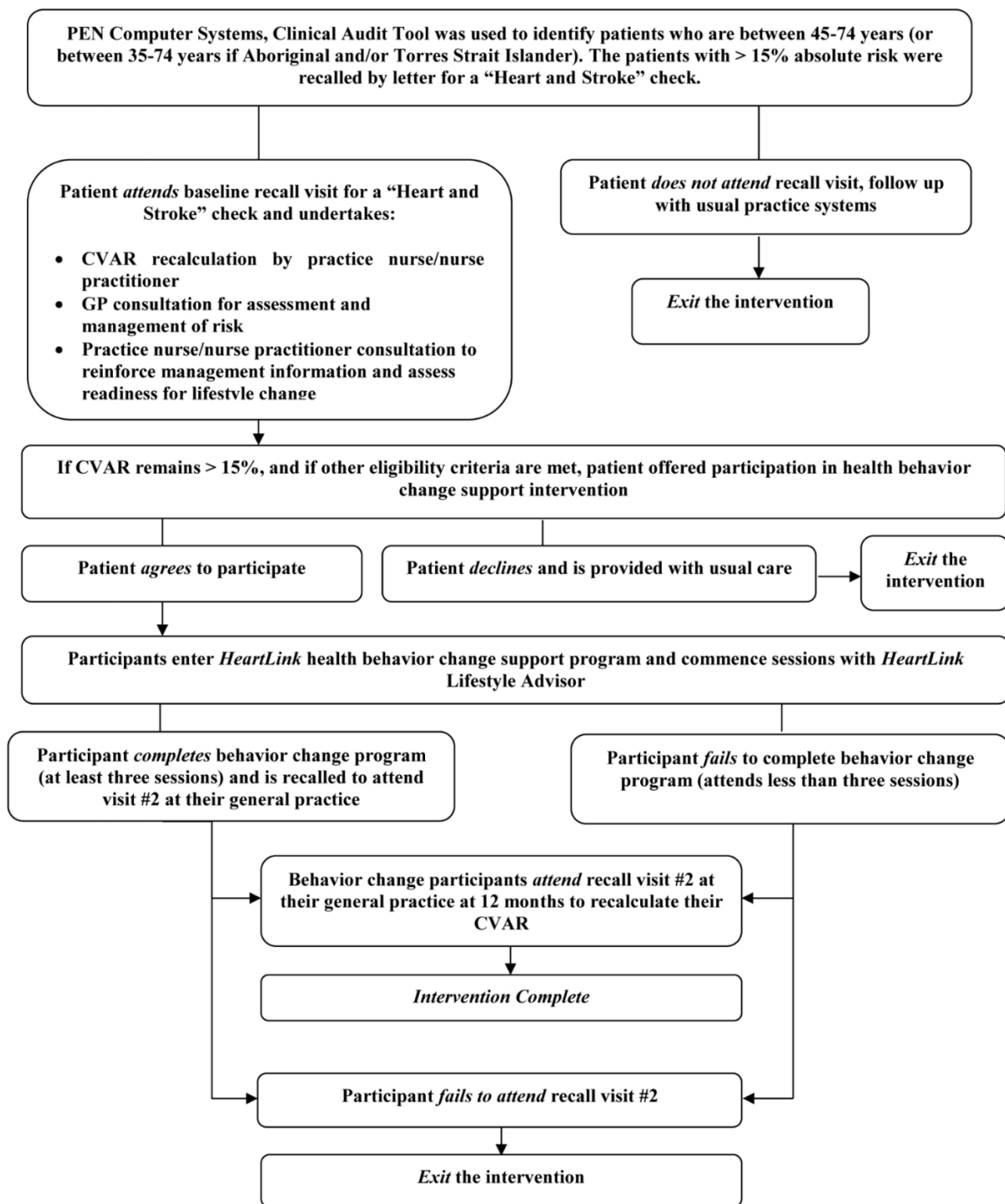
Aboriginal and/or Torres Strait Islander people), have a CVAR >15% over the next five years, and an absence of established CVD, diabetes, or a previous cardiovascular event to be included. Patients were excluded if they had not attended the general practice in the last two years, had a complex coexisting medical condition or impairment, were non-English speaking, or were excluded from the intervention by their general practitioner.

The patients participating in the intervention will be recruited through their usual general practice. Each of the pilot general practices uses a clinical software program to manage patient information and possesses a clinical audit tool. The clinical audit tool has a CVD risk calculator report function that generates a list of patients (from the clinical software records) meeting the CVAR inclusion criterion of associated risk level. The CVAR calculator uses age, gender, systolic blood pressure, smoking status, and serum lipids to calculate risk. A history of left ventricular hypertrophy and having diabetes are also identified.

An initial list of patients with a CVAR > 15% will be generated for each practice, and from this list random subsamples in batches of around 20 patients (the actual number depending on practice size and available resource) will be generated at scheduled intervals. As each sample is identified, the invitation letters will be posted (with up to two reminders) to invite participants to attend their practice for a “heart and stroke check”. Those attending the practice for the check will be offered participation in a health behavior change program if they are eligible. The scheduled sampling will occur over a six month period until the target sample size is achieved. [Figure 2](#) shows the *HeartLink* participant pathway.

The University of Canberra’s Human Research Ethics Committee approved this study (Project number 11-141).

Figure 2. HeartLink pilot participant pathway. CVAR: cardiovascular absolute risk, GP: general practitioner.



HeartLink Intervention Description

Enhanced Usual Care in General Practice for Patients at High Risk of Cardiovascular Disease

The aims of the *HeartLink* pilot are to work with general practices to enhance care in relation to identification, recall, assessment, and management of patients at high risk of CVD. The intervention follows the evidence-based “5A’s” approach, with key steps integrated across the pilot design [26]. Upon recruitment, support will be provided to all of the participating general practices to audit their patient data, establish or improve

data quality processes, and, where required, encourage processes to improve the levels of preventative activities such as measurement and recording of patient blood pressure. These actions are expected to maximize the patient numbers for recruitment, and will support the broader aims of the pilot to improve systems for the prevention and management of CVD in the pilot practices.

The PEN Computer Systems Pty Clinical Audit Tool CVD risk report will be used for the population of each practice, except those not attending the practice for more than two years, as it is likely that they are no longer patients of the practice or do

not have a regular general practitioner (GP) at the practice. The patients identified as having a risk score of >15% on their most recently recorded clinical information will be sent a letter asking them to visit for a “heart and stroke” check [4]. The patients whose most recent cholesterol measures are greater than six months old will be sent a pathology request form along with their recall letter to encourage them to update their lipid levels before they attend their recall visit.

When patients arrive for their recall visit, they will have their CVAR recalculated by the practice nurse before a consultation with their GP.

As part of the recall visit to the general practice at baseline and 12 months, the CVD risk factor information required to calculate the absolute risk will be collected. The practice nurse in the clinical environment will measure the blood pressure, and the cholesterol level measurement (total and high-density lipoprotein cholesterol) will have been undertaken by a commercial pathology service provider upon referral from the GP prior to the visit. The smoking status, defined as smoker or nonsmoker (self-reported), will be recorded.

The GP consultation will comprise the usual care in relation to the management of the patient’s CVD risk profile, including making referrals to allied health professionals or medical specialists as required. GPs and practice nurses in participating practices will be offered professional development with regards to CVAR management guidelines, and will be provided with copies of the guidelines. After the GP consultation, the patient then returns to the practice nurse to consolidate the information provided by the GP. The patients will receive a brief intervention related to lifestyle modification and medication adherence, supported by Heart Foundation print material. The practice nurse consultation will be informed by the Health Change Australia (HCA) approach to health behavior change, and will aim to improve patient readiness for lifestyle change [27,28]. *HeartLink* uses the HCA approach across the intervention to provide patients with a consistent health behavior change paradigm, reinforced at each contact.

The eligible patients will then be offered participation in the health behavior change support program. If patients do not wish to progress to the program or are deemed by their GP to be

ineligible, they will be given information on other health behavior change support options and offered ongoing usual care. The eligible patients who are initially not prepared to participate in the program will be provided with an opportunity to join the program at a later stage if they recontact their general practice within the recruitment timeframe of six months. The patients who are eligible and agree to participate in the health behavior change support program will be referred to the *HeartLink* Lifestyle Advisor linked to their practice.

Health Behavior Change Support Program

After referral, participants will enter into a program of health behavior change support for an average of three to six sessions over a period of up to 12 months. The completion of three sessions has been identified as sufficient time to progress key aspects of the HCA approach and achieve a moderately intensive program. These sessions will be held with Lifestyle Advisors who are fitness professionals and experienced leaders in the Heart Foundation “Heartmoves” program [29]. The Lifestyle Advisors will undertake training in the HCA approach to health change, and receive ongoing professional development sessions from HCA staff.

A short summary report will be provided back to the patient’s GP after the baseline, third, and final sessions. The advisors will connect patients with existing community resources, such as lifestyle modification programs and services to support their behavior change goals as appropriate. The advisors will also work to build relationships with local community-based providers to ensure they meet the needs of their patient cohort, and support the providers to develop systems to achieve better linkages to general practice.

Building an Improved Cardiovascular Disease Prevention System

Support to develop better systems for prevention of CVD will be provided to the general practice, allied health, and community sectors involved in the intervention. These activities align broadly with the elements of the ECCM. The table below provides a summary of these activities, and was based on a similar table developed for the Racial and Ethnic Approaches to Community Health program [10].

Table 1. Summary of *HeartLink* activities.

ECCM element	General practice activities	Community sector activities (outside general practice)
Decision support	Professional development on a CVAR assessment and management guidelines for all general practice staff.	Professional development on relevant aspects of CVAR assessment and management for allied health and lifestyle modification program providers.
	Identify decision support strategies for CVAR guidelines implementation using clinical software and complementary resources.	Identify and support the role of community-based providers in supporting the assessment and management of CVAR.
Information systems	Undertake ongoing quality activities to improve risk factor data collection and recording.	Review community and allied health information systems and identify opportunities for quality improvements related to relevant aspects of CVAR risk assessment and management.
	Develop reporting, recall, and monitoring processes for CVAR assessment of the patient population.	Identify community information systems to support community sector decision making.
Delivery system design/ reorientate health services	Develop mechanisms to improve linkages between general practices and the allied health and community sector lifestyle modification services.	Develop mechanisms to improve linkages between community sector and allied health lifestyle modification services with general practices.
	Promote the role of general practice in prevention of CVD to practice populations.	Promote the role of allied health and community sector lifestyle modification services in CVD prevention.
Self-management/ develop personal skills	Lifestyle Advisor service to provide the connection between the patient, general practice, and the community sector.	Develop and support a network of community-based lifestyle related service providers with an interest in CVD prevention.
	Deliver professional development activities to improve the health behavior change skills of general practice staff.	Deliver professional development activity to improve health behavior change skills of community sector lifestyle providers and allied health professionals.
Build healthy public policy	Map relevant national and local policy to understand aspects that support or impede the intervention approach.	Map relevant local and national policy and programs to understand aspects of policy that support and impede the intervention approach.
Create supportive environments	Promote community initiatives that are working to create supportive environments for healthy lifestyles in the general practice setting.	Develop connections with existing community initiatives that are working to create supportive environments for healthy lifestyles.
Strengthen community action	Promote the <i>HeartLink</i> intervention activities through general practice populations.	Promote the <i>HeartLink</i> intervention to the community through various media and community network channels.
	Provide opportunities to create connections between health care professionals and community organizations.	Provide opportunities to create connections between community organizations and health care professionals.

Data Collection

Primary Health Outcome Measure

The primary health outcome measure for the study will be the change in the CVAR percentage score for the *HeartLink* intervention participants. A range of patient-reported health and well being outcomes will also be examined, including physical activity levels, fruit and vegetable intake, CVD medication adherence, health related quality of life, generalized self-efficacy, and intention to change key health behaviors related to CVD risk reduction.

Individual Health and Well Being Data

Health related data will be collected from all *HeartLink* patients using validated tools via a paper-based survey administered at baseline and at 12 months. The survey will determine: (1) Physical activity levels, the usual physical activity levels will be collected via the Active Australia survey, which has been reported as reliable and having acceptable validity within an adult Australian population [30]. (2) Fruit and vegetable intake,

the number of servings of fruit and vegetables will be assessed using validated questions from the National Nutrition Survey [31]. (3) Medication adherence, the participant's adherence to the prescribed medication (antihypertensive and lipid lowering medication) is an important factor in reducing cardiovascular risk [32]. The participant's adherence to CVD related medication (if medication has been prescribed) will be assessed using the four-item Morisky scale for each category of medication [33]. (4) Quality of life, the health related quality of life will be assessed using the short form (SF)-12v2 Health Survey (SF12 v2). The SF12 v2 is a validated and commonly used tool that provides insight into mental and physical functioning and overall health related quality of life [34]. (5) Generalized self-efficacy measure, a validated generalized self-efficacy measure, the General Self-Efficacy Scale will be used, as self-efficacy is an important determinant of behavior change. While a number of tools have been developed to measure self-efficacy in relation to specific health promoting behaviors, a generalized self-efficacy measure was selected, given that each patient will be choosing which particular health behavior or behaviors they are ready to change [35]. And (6) Intention for lifestyle change

measure, several validated questions related to key lifestyle change measures for CVD risk reduction, such as dietary changes, alcohol intake, and smoking, and based on the transtheoretical model of behavior change will be included. The lifestyle change messages are all included in the Heart Foundation printed education material provided to each intervention participant [36].

Patient Focus Groups and Semistructured Interviews

To complement the quantitative data collection, focus group discussions or semistructured interviews will be held at the completion of the health behavior change support program. The participants of the health behavior change support program will be invited to participate in focus groups or semistructured interviews. This will allow a detailed examination of the behavior change intervention experience from the participant's perspective. The patients who were recalled to their practice for a "heart and stroke check", who did not attend the practice for the check, will also be invited to participate in semistructured interviews to examine the reasons for their nonattendance, and their experience of receiving the recall letter. The focus group sessions or interviews will be conducted until the saturation of themes is achieved, that is, no new major themes are detected.

System Related Data- Case Study of HeartLink

Multiple data sources will be used to examine the complex range of system-related issues in the case study.

Focus Groups, Semistructured Interviews, and Key Informant Forum

The focus group discussions or semistructured interviews will be conducted with key stakeholder groups over the course of the study, including with general practice staff, Lifestyle Advisors, allied health professionals, and community-based lifestyle modification program providers. These discussions will aim to identify themes in relation to the research questions, and will also provide an opportunity to engage key individuals and groups in the intervention process. Purposive sampling will be used to ensure key informants in each stakeholder group are represented. The goal will be to recruit at least eight people for each of the focus groups. The topic guides will be developed using key issues identified from the literature, including the critical success factors for systems thinking in prevention of chronic disease, and key constructs for understanding implementation of complex interventions [37,19].

The topic guides will provide an initial direction for the discussions. A forum with key policy and program informants from the primary health care sector will be conducted near the completion of the *HeartLink* intervention to gain feedback on the policy and program implications of the findings, and to provide input into the emergent CVD prevention model.

An open-ended questionnaire will be used to gather the views of the key informants.

Primary Health Care and Chronic Disease Prevention Policy and Program Documents

Document analysis is commonly used in case study research as an additional source of evidence, and as a means of triangulation

[22]. The key national and local primary health care and chronic disease prevention policy documents will be examined. The documents reviewed will include the National Primary Care Strategy, the National Primary Health Care Strategic Framework, and the National Prevention Taskforce's National Preventative Health Strategy [38-40]. This analysis aims to provide information on the macro and meso-systems context in which the *HeartLink* intervention is occurring, provide a means of tracking change in relevant issues over the intervention period, and to verify findings or corroborate other evidence collected as part of the study [41].

Reflective Diaries of Lifestyle Advisors

Lifestyle Advisors will keep reflective diaries for the duration of the *HeartLink* intervention. The role of the advisor is similar to that of the "boundary spanner", as described by Etz, providing a connection between the general practice and community sector, thus offering insight into the linkage process between the sectors [42]. The advisors will be encouraged to record issues related to patients, the general practice, and their work with community lifestyle modification providers. They will be also encouraged to reflect on their own practice, and will be given a set of prompt questions encouraging them to consider barriers, enablers, opportunities, and threats for the future implementation of the intervention approach. The diaries will be reviewed regularly to ensure data quality, and will be collected at the completion of the intervention.

Intervention Process Measures

The system's outcomes will be further examined using a range of process measures. One of which is a brief audit to assess the degree of implementation of the CVD prevention system elements by each stakeholder group. A specific audit tool will be developed for the three key stakeholder groups: (1) general practice, (2) community-based allied health professionals, and (3) other lifestyle modification program providers based on the Assessment of Chronic Illness Care tool [43].

Data Analysis

Quantitative Data Analysis

Changes in the CVAR will be reported at the total practice population level, but also analyzed by each practice. The primary analysis will be done on an Intention to Treat basis. The CVAR was chosen as the primary health outcome, as it represents an all around measure of the *HeartLink* intervention's ability to meet its objectives.

An analysis of the quantitative data collected from the clinical data and the participant survey will be undertaken. Univariate comparisons between the pre and post intervention groups will be conducted using a chi-square test for equal proportion (or Fisher's exact tests where numbers are small), and reported as numbers and percentages. Continuous normally distributed variables will be compared using student's *t* tests and reported as means (95% confidence interval). Nonnormally distributed data will be compared using Wilcoxon signed rank tests.

The *HeartLink* pilot data will be used to estimate population proportions (and confidence intervals) for those at high risk of CVD in the ACT. This data will also generate planning

information for a future larger study. The intercluster correlation coefficient, effect size, and standard deviation will be examined to help determine sample size calculations, cluster size, and number of clusters.

Qualitative Data Analysis

The thematic analysis of focus groups, semistructured interviews, reflective diaries, and key policy and program documents will be undertaken. A mixed deductive and inductive approach will be used for the analysis, which allows for initial codes to be identified from the literature, and knowledge and experience of the research team [44]. These codes will then be revised, reviewed, replaced, and added to, from the data. This process provides the inductive aspects of the analysis. Consistent with a convergent parallel mixed methods design and case study approach, the data analysis stage will include the integration of the data once the primary analysis is complete [45]. This approach will allow for the triangulation of the data to enhance validity, will help to describe the complex multi-strategy nature of *HeartLink*, and could enlighten areas of interest and relevance where empirical outcomes are not clear. This integrated analysis will be presented as the case study narrative, informing the development of the implementation model.

Results

The *HeartLink* intervention is complete, with post intervention data collection currently underway. The results are expected in late 2015.

Discussion

The Model for Prevention Study

This protocol seeks to provide a detailed description of the MoFoP study, which will examine a whole-of-system CVD prevention intervention in primary health care. It will aim to identify key elements of an effective model and implementation strategies to inform better practice in this key health priority area for Australia. A recent systematic review of interventions aimed at enhancing best practice in primary health care for chronic disease management, prevention, and episodic care found that multiple and linked strategies targeting the system, practice, and community level are most likely to improve access for patients to best practice [46]. The *HeartLink* intervention, which is the focus of the MoFoP study, adopts an intersectoral and multi-level approach, which aligns with findings of this review.

Gaining a better understanding of CVD prevention in primary health care requires a research approach that can capture and express its complexity. By choosing a mixed methods research design and using the complementary case study and experimental approaches, we aim to provide a comprehensive picture of the study outcomes. While there are a number of challenges in effectively capturing the many layers in a “real life” intervention, the potential for findings to have more rapid translation into policy and practice because they present a more complete and pragmatic understanding of issues makes the approach worth pursuing.

By bringing together a range of issues of interest to contemporary primary health care, the MoFoP study provides a timely appraisal of the use of a CVAR approach to CVD prevention, the evolving role of the primary health care sector, and evidence-based approaches to supporting lifestyle change. These issues align with the current health reform agenda in Australia that commits to a reorientation of health services for a stronger preventative focus and rededication to the ideals of primary health care [38].

Finally, the MoFoP study uses existing models for improvements in chronic disease prevention as its working framework. The ECCM in particular provides a vision for an integrated, whole-of-system and intersectoral approach to CVD prevention. By developing an intervention that addresses the key elements of this model, and then undertaking a comprehensive exploration of the intervention outcomes, we hope to explore the potential to further develop the ECCM model, improving its applicability to CVD prevention in the Australian primary health care context. We also hope that an enhanced model based on the study findings will be a valuable additional outcome from the study, and will facilitate the communication and implementation of knowledge gained from this study.

Limitations of the Study Protocol

There are a number of limitations of this study. Case study approaches have often been criticized for their lack of generalizability, and their lack of rigor. To address this, a sound research design has been developed that follows a logical process [22]. The multiple sources of data and the addition of the preexperimental component should add rigor by allowing the cross-validation of the interpretation of the study findings.

The *HeartLink* intervention itself has limitations that include the small scale of the intervention, “opt in” in the sample of practices, and the intervention occurring in one relatively small city of approximately 340,000 people. Given its pragmatic design, the study has limitations in standardizing some aspects of the intervention protocols and data collection, within busy general practices with a varied workforce and a wide range of skill sets. That acknowledged, the MoFoP study and the *HeartLink* intervention are designed to inform a larger cluster randomized controlled trial to evaluate the effectiveness of using a larger number of control and intervention practices, and to better understand the effectiveness and generalizability across the primary health care sector as a whole.

Conclusions

The MoFoP study will examine a whole-of-system CVD prevention intervention that supports patients from risk identification through to clinical and lifestyle issues management, from general practice and into the community. By considering existing chronic disease prevention models and undertaking a holistic investigation of the *HeartLink* “case”, the MoFoP study aims to build understanding and propose new directions for this complex area of primary health care. Given the size of the problem and the current evidence to practice gap, it is an area worthy of exploration, and its outcomes should be of interest to both practitioners and policy makers.

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Authors' Contributions

NV led the development of the design of the study protocol, drafted and finalized the manuscript. RD, TC, LW, and TCI participated in the design of the study protocol, and helped to draft relevant sections of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ACT: Australian Capital Territory
CCM: Chronic Care Model
CVAR: cardiovascular absolute risk
CVD: cardiovascular disease
ECCM: Expanded Chronic Care Model
GP: general practitioner
HCA: Health Change Australia
MoFoP: model for prevention
SF: short form

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Protocol

Patient Safety Policy in Long-Term Care: A Research Protocol to Assess Executive WalkRounds to Improve Management of Early Warning Signs for Patient Safety

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Abstract

Background: At many hospitals and long-term care organizations (such as nursing homes), executive board members have a responsibility to manage patient safety. Executive WalkRounds offer an opportunity for boards to build a trusting relationship with professionals and seem useful as a leadership tool to pick up on soft signals, which are indirect signals or early warnings that something is wrong. Because the majority of the research on WalkRounds has been performed in hospitals, it is unknown how board members of long-term care organizations develop their patient safety policy. Also, it is not clear if these board members use soft signals as a leadership tool and, if so, how this influences their patient safety policies.

Objective: The objective of this study is to explore the added value and the feasibility of WalkRounds for patient safety management in long-term care. This study also aims to identify how executive board members of long-term care organizations manage patient safety and to describe the characteristics of boards.

Methods: An explorative before-and-after study was conducted between April 2012 and February 2014 in 13 long-term care organizations in the Netherlands. After implementing the intervention in 6 organizations, data from 72 WalkRounds were gathered by observation and a reporting form. Before and after the intervention period, data collection included interviews, questionnaires, and studying reports of the executive boards. A mixed-method analysis is performed using descriptive statistics, *t* tests, and content analysis.

Results: Results are expected to be ready in mid 2014.

Conclusions: It is a challenge to keep track of ongoing development and implementation of patient safety management tools in long-term care. By performing this study in cooperation with the participating long-term care organizations, insight into the potential added value and the feasibility of this method will increase.

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KEYWORDS

governance, long-term care, executive board, patient safety, WalkRounds, soft signals

Introduction

Good quality of care and patient safety require leadership involvement from both professionals and managers [1-6]. However, analyses of recent safety incidents in health care in the Netherlands show that there is a lack of governance on patient safety [7]. This is related to the fact that allocation of responsibilities for patient safety between professionals and managers is not clearly defined, and that board members, who have the final responsibility, lack leadership tools to improve and secure patient safety at an organizational level [7].

Currently available tools for the management of safety in health care are largely based on quantitative management information. Dashboards/scorecards and quality indicators emerge as a vital tool for hospital leaders who promote quality improvement within their organizations [5]. However, these tools do not paint the whole picture and, on their own, do not yield sufficient information to monitor quality and patient safety [8]. Vaughn et al [6] showed that having access to this information is only 1 of 5 characteristics of hospital boards that are associated with better quality index scores in hospitals. Spending more than 25% of time on quality issues, basing the senior executive's compensation in part on quality improvement performance, identifying the chief executive officer as the person with the greatest impact on quality improvement, and engaging in a high level of interaction with the medical staff on quality strategy are the other 4 characteristics of hospital boards with better quality index scores.

In addition, Twijnstra and Gudde [9] identified the professional relationship between board members and professionals as an important precondition for safety policy in hospitals and in long-term care settings. This relationship should be based on mutual trust to allow the board to pick up on indirect signs (eg, conflicts between the medical staff or discontent of staff members). These so-called soft signals are important early warnings that something is wrong. They can supplement or confirm current management information and seem useful as a leadership tool for board members.

In 1999, the Institute for Healthcare Improvement initiated Executive WalkRounds. Frankel conceptualized these Executive WalkRounds as a tool to engage senior management in patient safety and to build a culture of safety within the organization [1,10]. Executive WalkRounds are conducted in patient care departments and provide an informal method for leaders to talk

about safety issues in the organization with front-line staff and show their support for reporting errors [11]. According to Frankel [1,2,11], using these Executive WalkRounds allows senior executives of health care organizations to demonstrate commitment to building a culture of patient safety, provide opportunities to learn about patient safety, identify opportunities for improving safety, and establish lines of communication about patient safety with personnel. Research showed that Executive WalkRounds improved the safety culture in hospitals (eg, during 8 months, 39% of the patient safety issues were resolved) and added to the trust that the board was there to support and listen to professionals of all levels [2,12]. Executive WalkRounds are therefore considered to be an effective method to capture soft signals and a way to enhance the mutual trust between professionals and the board.

The majority of the research on patient safety and Executive WalkRounds has been performed in hospitals. It is therefore unknown how board members of long-term care organizations develop their patient safety policy. In addition, it is not clear if these board members use soft signals as a leadership tool and if so, how this influences their patient safety policy.

The aim of this study was to introduce and evaluate the method of Executive WalkRounds in long-term care organizations in the Netherlands to explore the added value and the feasibility of this method for picking up soft signals. In addition, this study aimed to identify how board members of long-term care organizations manage patient safety and to describe the characteristics of the boards.

Methods

Study Design and Setting

An explorative before-and-after study was conducted in long-term care organizations in the Netherlands between April 2012 and February 2014. We included 13 organizations that varied in size and were spread across rural and urban locations in the Netherlands (Table 1).

Before the introduction of Executive WalkRounds, data collection took place in the included long-term care organizations to identify the characteristics of boards of the organizations. Then, the intervention was implemented in 6 organizations during 1 year. After this period, the added value of managing soft signals on patient safety outcomes was investigated in all participating organizations.

Table 1. Characteristics of the participating organizations.

Health care sector	Size	Geographic location/urban or rural	No. of patients
Mental health	13 locations	West/urban	11,368
Mental health	3 regions	Mid East/urban	20,489
Mental health	6 locations	Mid South/rural	16,602
Mental health	20 locations	North/rural	18,029
Nursing home	19 locations	Mid West/urban	3389
Nursing home	3 locations	Mid/rural	246
Nursing home	2 locations	North West/rural	289
Nursing home	20 locations	Mid South/rural	2006
Nursing home	18 locations	Mid/urban	10,992
Physically and intellectually disabled	11 regions	Mid/urban and rural	2804
Physically and intellectually disabled	10 locations	Mid South/urban and rural	2523
Physically and intellectually disabled	43 locations	East/urban and rural	2047
Physically and intellectually disabled	400 locations	North/urban and rural	3188

Ethical Aspects

The study was assessed by the Medical Ethics Committee of the district Arnhem – Nijmegen in the Netherlands. They concluded that, according to Dutch Law, this study was deemed exempt from their approval because it did not include collection of data at the level of patients.

Participants and Sample

Convenience sampling was used to include a diverse group of long-term care organizations. We include 4 mental health care institutions, 5 nursing home and home care organizations, and 4 institutions for the physically and intellectually disabled. After written informed consent, the organizations were nonrandomly assigned to an intervention and a control group. The intervention group in which the method of Executive WalkRounds was introduced included 2 mental health care institutions, 2 nursing home and home care organizations, and 2 institutions for the physically and intellectually disabled. The other organizations (n=7) formed the control group and continued care as usual.

Intervention

Overview

The development and introduction of the intervention had three stages: (1) modifying the original concept; (2) developing a standard script; and (3) introduction of the intervention.

Stage 1: Modifying the Original Concept

To promote the feasibility of the Executive WalkRounds in long-term care, we reviewed and modified the original concept developed by Frankel et al [2] (Table 2).

To promote the usability of the name and method we shortened the name to WalkRounds. We developed ground rules (Table 3) and translated the original “initial questions” for the WalkRounds developed by Frankel [2] and Cavanagh and Hulme [13] into Dutch. Furthermore, we added the possibility to extend the attendees (“with whom”) with patients, family, and relatives. Finally, the frequency was changed to monthly and WalkRounds were conducted by an interdisciplinary team at board level (eg, chairperson of the board, senior manager, senior quality improvement, and medical director).

Table 2. Original concept of WalkRounds.^a

Who	Senior executives or vice presidents, the patient safety manager, a quality department director, the pharmacists assigned to the area, and a research assistant
Frequency /duration	Weekly/approximately 1 hour
Where	At the workplace of different areas of the hospital; eg, medical ward, surgical ward, emergency department or laboratory. In an open area to increase visibility.
With whom	Nurses and other available staff; eg, patient care assistants, and attending or resident physicians
Initial questions asked during the WalkRounds	<ol style="list-style-type: none"> 1. Were you able to care for your patients this week as safely as possible? If not, why not? 2. Can you describe how communication between caregivers either enhances or inhibits safe care on your unit? 3. Can you describe the unit's ability to work as a team? 4. Have there been any "near misses" that almost caused patient harm but didn't? 5. Is there anything we could do to prevent future adverse events? 6. What do you think this unit could do on a regular basis to improve safety? 7. When you make an error, do you always report it? 8. If you prevent/intercept an error, do you always report it? 9. If you make or report an error, are you concerned about personal consequences? 10. Do you know what happens to the information that you report? 11. Have you developed any personal practices that you carry out to specifically prevent making errors? 12. Have you discussed patient safety issues with your patients or their family? 13. Do patients and families voice any safety concerns? 14. What specific intervention from leadership would make the work you do safer for patients? 15. What would make these executive WalkRounds more effective?
Recording	Comments on the questions are recorded on a worksheet.
Afterward	The senior executive briefly described a few of the important concepts that will lead to a safer environment. In addition, participants are asked to tell 2 other staff members about the WalkRounds.
Key factor	To help participants develop a sense of "psychological safety" allowing them to speak openly during the rounds, confidentiality and anonymity must be guaranteed.

^aSee Frankel et al [2].

Table 3. Ground rules of WalkRounds.

Organizations should decide whether to deviate from the principle of announcing the time and place of the WalkRounds.
An agreed WalkRound is not canceled by the WalkRound team. The ward/unit may cancel a WalkRound in case of exceptional circumstances, such as emergencies or incidents. In this case, a new WalkRound will take place within 1 week.
The maximum duration of a WalkRound is 60 minutes.
WalkRounds take place on the floor of a patient care unit; ie, office, recreation room.
All information discussed in WalkRounds is strictly confidential.

Stage 2: Developing a Standard Script

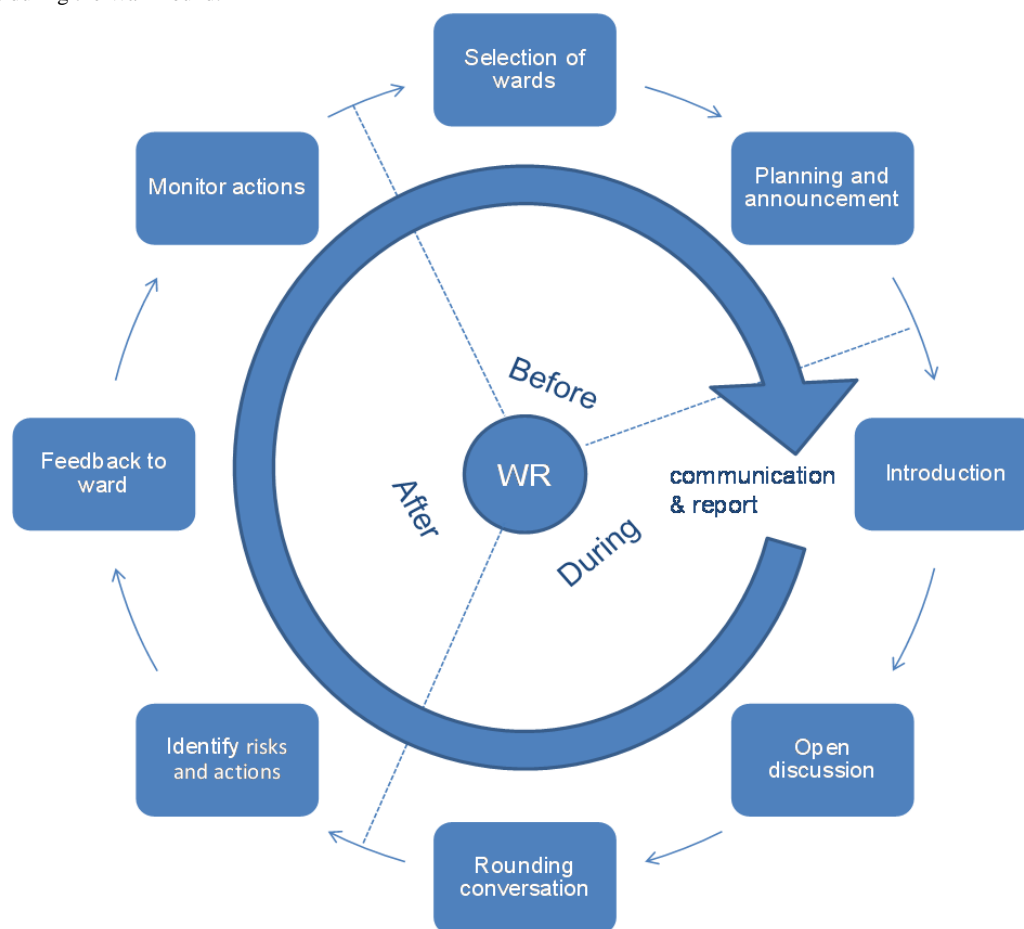
Based on the literature concerning Executive WalkRounds [2,3,11-14] we developed a standard script to facilitate the intervention. This standard scripts consisted of the introduction; the background; the procedure (ie, ground rules and the three phases; [Figure 1](#)); starting, final, and additional questions; and the reporting form.

We decided that each WalkRound lasted 30-60 minutes. An open discussion about patient safety was encouraged to hear the views of all present; staff, patients, family or relatives. From the original questions, we determined a standard starting question and a final question that we encouraged. These questions are "can you describe any near misses that almost

caused patient harm, that occurred sometime during this week?", and "what do you think this unit could do on a regular basis to improve safety?"

After the WalkRound was completed, the WalkRound team reflected on the visit and reported the salient points such as the soft signals and safety risks, and agreed upon the improvement actions. Urgent problems had to be solved within 24-48 hours in collaboration with the board. The lead of the WalkRound team reported the patient safety issues to those responsible in the board on a regular basis.

Except for the ground rules, the starting and final questions, and the report form, the WalkRound teams had the opportunity to modify the standard script to their own setting and population.

Figure 1. Phases during the WalkRound.

Stage 3: Introduction of the Intervention

To introduce the intervention, each WalkRound team participated in a workshop of 3 hours in which they learned about the method and made working agreements to implement the WalkRounds in their organizations. To enhance the feasibility of the method, we did not enforce one standard script for the participating WalkRound teams. After the workshop, the WalkRound team decided which unit they would visit and ensured clear communication in the organization and the specific unit about aim and method. The WalkRounds were then announced, and during 1 year, the WalkRound team visited 6 different wards/units, including a follow-up visit per ward after 6 months.

Instruments

We use two types of instruments to collect data; instruments to collect data about the intervention (Table 4) and instruments to collect additional data (Table 5).

WalkRounds

To collect data on the WalkRounds (eg, duration, attendees, soft signals, and safety improvement activities) we developed a reporting form. To complement this form and collect data on the “psychological safety” (Table 1), a topic list was developed by the research team for collection of observational data about communication and ambience during the WalkRounds. We evaluated the feasibility of the method by conducting an open group interview with each WalkRound team. The opening

question of each group interview was “How did you experience the WalkRounds?” Topics for this interview, advised by an expert in the field of improvement strategies, were feasibility of the method, facilitators and barriers, and results on patient safety, trust, and communication.

To identify how executive board members manage patient safety and to describe the characteristics of the boards, we translated and adjusted the original instrument “the Executive QI Survey,” of Joshi [15]. This survey consists of 34 questions about Board Engagement in Quality; 11 closed questions with response categories on a scale of 0-10, and 23 open questions. The translation and adjustment to the Dutch situation was performed by 2 members of the research team. Experts in the field of health care management, and quality and patient safety determined face validity of the adjusted questionnaire. Based on their feedback, the questionnaire was split in a written questionnaire and a semi structured interview. The questionnaire consisted of 22 questions: 13 closed questions with a response scale of 0-10, 2 closed questions that require a yes or no answer, and 7 open questions. For instance “On a 1-10 scale, how satisfied are you that the quality data the board reviews are the right measures for a comprehensive assessment of the organization’s real quality performance?” or “For a typical meeting, what are the major Board standing agenda items?” The interview lasted 60 minutes and was based on 21 open questions; for example, “How do patient perspectives get incorporated into the Board’s agenda for quality and safety improvement?”.

In addition, we collected information from the meetings of the executive boards, using a topic list. The researcher and the 2 supervisors of the project developed the topic list that was based on the characteristics of hospital leadership engagement in quality improvement [6] and control modalities of safety risks [16]. For information about the topics, see the description in Table 4.

To describe the variation in patient safety policy between the participating organizations, data about characteristics of the

organizations are collected; that is, population, size, location, settings, number of clients and staff members, management vision, organizational structure, and allocation of responsibilities. To relate patient safety policy to better safety outcomes, we collected data from ZiZo, the Dutch framework of quality indicators [17]; especially the outcomes that focused on patient safety for 2011 and 2012. For systematic identification of new safety improvement activities, we used the framework developed by Hulscher et al [18]. This framework focuses on the content of the improvement activities.

Table 4. Data instruments for WalkRounds.

Instruments	Description
Reporting form	Information about duration, attendees, soft signals, risk assessment, and (the number of) safety improvement actions
Observation topic list	Information about communication and ambience
Open qualitative group interview	Feasibility of the method: experience in general, experienced results, barriers and facilitators, key factors regarding the influence of the WalkRounds

Table 5. Additional data instruments.

Topic	Description	Instruments
Characteristics of executive boards	Themes: amount of knowledge regarding quality and safety reports, agenda-setting, professionals, performance monitoring, responsibilities, values, and quality improvement activities	Questionnaire and semi structured interview (translated and adjusted from the Executive QI Survey [15])
Safety policy by executive boards	Frequency and duration of agenda items related to patient safety issues, signals about patient safety and instruments to collect these signals, the level of interaction with medical staff or health and safety committee on quality strategy, the safety culture, the allocation of responsibilities, and new safety improvement activities	Topic list (based on characteristics of hospital leadership engagement in quality improvement [6] and control modalities of safety risks [16])
Quality improvement activities	Information about the content of the activity, the participants, the executor, and whether the activity is based on soft signals detected during the WalkRounds	Framework of improvement activities [18]
Quality performance indicators	Indicators focusing on patient safety outcomes including the number and duration of seclusions and restraints, the duration of coerced medication, the percentage of patient falls, the percentage of medication incidents, the amount of weight loss, the percentage of patients with safety risks, and prevalence of safety incidents	Dutch framework of quality indicators [17] of mental health care, nursing home and home care, and care for the physically and intellectually disabled.

Data Collection

Overview

Data collection took place at 3 time points: (1) at baseline; (2) during the intervention period; and (3) at follow-up after the intervention period.

Baseline

Baseline data concerning characteristics of boards and their safety policy were collected from April through June 2012. We interviewed the board members (n=23) individually, asked them to fill out the questionnaire, and studied the reports of the board meetings (n=13).

Intervention Period

The intervention period ran from July 2012 until June 2013. During this period, information about the WalkRounds was collected in 2 ways. First, the chair of each WalkRound team filled out the reporting form per WalkRounds. Second, every

WalkRound was recorded on audiotape and observed by a member of the research team. In this way, we collected data about the communication and ambience. Because the 6 intervention organizations perform 12 WalkRounds each (1 per month), data from a total of 72 WalkRounds were gathered.

Follow-Up

Starting July 2013, data of the board were collected using the same instruments as used at baseline; for example, questionnaires, semi structured interviews, and by studying the reports focusing on patient safety and quality improvement, for July 2012 through June 2013. During this follow-up period, we also conducted open group interviews with the WalkRound teams to evaluate the method.

Data Analysis

Overview

The analysis consists of two main parts: analysis of the WalkRounds, and analysis of the additional data.

Analysis of the WalkRounds

Quantitative data regarding the organization of the WalkRounds; for example, duration and attendees, are analyzed using descriptive statistics. The reported soft signals and improvement activities are analyzed using content analysis. The researchers create a coding framework based on codes generated by Montgomery [12] for the soft signals, and Hulscher [18] for the improvement activities. The coding framework contains the code and an operational definition. The reported data are coded using this framework. During the analysis, data are independently interpreted and coded by the researcher and research assistant. In case of disagreement, consensus is reached through discussion. The open group interviews regarding the evaluation of the WalkRounds are analyzed similarly. The coding framework for analyzing the group interviews is based on the items “added value and feasibility,” “trust and interaction,” and “implementation.”

Analysis of the Additional Data

Quantitative data regarding characteristics of the organizations, characteristics of the board, and the way board members manage patient safety are analyzed using descriptive statistics. For a comparison of the average number of safety improvement activities, within and between the intervention and control groups, *t* tests are computed; a $P < .05$ is considered statistically significant. In addition, *t* tests are computed to evaluate the influence of the intervention by comparing the patient safety performance indicators within and between the intervention and control groups.

Important texts that emerge from examination of the questionnaires and interviews are analyzed using qualitative content analysis. The reports are analyzed both quantitatively using descriptive statistics and qualitatively using open, axial, and selective coding [19], based on the coding manual. During each phase of coding, data are independently interpreted and coded by the researcher and research assistant. In case of disagreement, consensus is reached through discussion.

We use SPSS version 18 and ATLAS.Ti version 6.2 for the quantitative and qualitative data analysis, respectively.

Discussion

Challenges

The currently available tools for managing safety in health care do not appear to yield sufficient information to monitor patient safety [8]. In addition, soft signals seem useful as a leadership tool to supplement current management information [9]. Executive WalkRounds are thereby considered to be an effective method to capture these soft signals. However, to our knowledge, research on WalkRounds in which the board of long-term care organizations focus on soft signals has not yet been done. Therefore, the effect of WalkRounds on patient safety policy in long-term care is not known.

This study posed several challenges concerning studying the added value of managing soft signals by WalkRounds. First, because of the incentives of the national government to improve patient safety, organizations in the control group will also invest

in patient safety during this study period. These organizations will probably invest in patient safety through other ways of quality improvement such as internal audits, or implementing a safety management system. Because of these initiatives, care as usual will change during the study period. In addition, organizations implementing WalkRounds may be required to use other safety promotion methods as well. Therefore, it will be difficult to compare the exact effects of WalkRounds.

Another challenge we want to discuss is the ongoing development of quality measuring instruments in the Netherlands. First, since 2013, nonprofit health care trade associations are responsible for developing their own quality indicators and data infrastructure because ZiZo, the Dutch framework of quality indicators, will no longer exist [20]. Possible consequences are that data on patient safety outcomes for 2012 are not yet available at the end of our study period, or data differ from 2011. Therefore, gathering data or comparing data of the influence of WalkRounds to safety outcomes might be difficult. Furthermore, development of vision on quality and patient safety results in a shift from quantitative management information toward process indicators as management tools. For example, the association of mental health care implemented a patient safety program between 2008 and 2011, which focused on process indicators to prevent or reduce adverse events. Implementation of the 7 goals (presence of protocols to prevent or reduce, eg, the number of restraints or seclusions, aggression, and suicide) of this program is still ongoing in the mental health care institutions. Since 2008, the association of nursing home and home care organizations also implemented patient safety improvement programs. They determined 5 focal points including implementing standards of responsible care, and improvement programs managing medication safety, preventing falls, or physical restraint. Furthermore, the association of the physically and mentally disabled defined 5 new issues for their patient safety agenda, including promoting the reporting of incidents, training risk awareness, and specific programs for example aimed at sexual harassment and abuse [21]. We consider this shift an opportunity for the long-term care to manage patient safety in a way that better fits the specific populations under care. On the other hand, because of these social dynamics in long-term care, it will be difficult to collect the same outcomes before and after the intervention period.

Limitations

The methodological limitations of this study must be considered. First, there is a considerable diversity in the participating organizations; they vary in size, population, and rural and urban location. Although this may hinder comparisons in this study, we believe it also strengthens the evidence for the feasibility of the WalkRounds in the long-term care setting. Second, because of the small sample size of this study, the representativeness of the findings is at risk. Because exploration of the value and feasibility of WalkRounds is our primary goal, we believe that using a diverse sample will allow us to say something about all types of organizations, which in this case will contribute to representativeness. Third, due to the convenience sampling, potential confounding factors can threaten the internal validity [19]. The selection of the included organizations, and the nonrandom assignment to the intervention and control group

can influence the outcomes of the study positively. Those who are willing to participate in this study may be atypical of the population due to their drive to improve patient safety policy. To minimize this threat, potential confounding factors and their impact on the interpretation of the study results will be identified by collecting baseline data of the organizations' characteristics,

the same data before and after the intervention period, and data of the trade specific quality measuring instruments.

Despite these limitations, we think that by performing this study in cooperation with the participating long-term care organizations, we will increase the insight into the potential added value of managing soft signals by WalkRounds and the feasibility of this method in long-term care.

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Conflicts of Interest

None declared.

Authors' Contributions

LvD wrote the article, coordinated the study, prepared instruments for the study, collected and analyses the data. LS wrote the article, developed the study, and is the general supervisor of the study. HH wrote the article, participated in the development of the study, approached the participating organizations, and is supervisor of the study. TvA wrote the article and participated in the development of the study. All authors approved the final manuscript.

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Protocol

A Design to Investigate the Feasibility and Effects of Partnered Ballroom Dancing on People With Parkinson Disease: Randomized Controlled Trial Protocol

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Abstract

Background: Self-help and physical leisure activities has become increasingly important in the maintenance of safe and functional mobility among an increasingly elderly population. Preventing the cycle of deterioration, falling, inactivity, dependency, and secondary complications in people with Parkinson disease (PD) is a priority. Research has shown that people with PD are interested in dance and although the few existing trials are small, initial proof of principle trials from the United States have demonstrated beneficial effects on balance control, gait, and activity levels. To our knowledge, there has been no research into long-term effects, cost effectiveness, the influence on spinal posture and turning, or the personal insights of dance participants.

Objective: The purpose of this study was to determine the methodological feasibility of conducting a definitive phase III trial to evaluate the benefits of dance in people with PD. We will build on the proof of principle trials by addressing gaps in knowledge, focusing on areas of greatest methodological uncertainty; the choice of dances and intensity of the program; for the main trial, the availability of partners, the suitability of the currently envisaged primary outcomes, balance and spinal posture; and the key costs of delivering and participating in a dance program to inform economic evaluation.

Methods: Fifty participants (mild-to-moderate condition) will be randomized to the control (usual care) or experimental (dance plus usual care) groups at a ratio of 15:35. Dance will be taught by professional teachers in a dance center in the South of England. Each participant in the experimental group will dance with his or her spouse, a friend, or a partner from a bank of volunteers. A blinded assessor will complete clinical measures and self-reported ability at baseline, and at 3 and 6 months after randomization. A qualitative study of a subgroup of participants and partners will examine user's views about the appropriateness and acceptability of the intervention, assessment protocol, and general trial procedures. Procedures for an economic evaluation of dance for health care will be developed for the main trial.

Results: Recruitment began in January 2013 and the last participant is expected to complete the trial follow-up in June 2014.

Conclusions: Findings from our study may provide novel insights into the way people with PD become involved in dance, their views and opinions, and the suitability of our primary and secondary outcomes.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 63088686; <http://www.controlled-trials.com/ISRCTN63088686/63088686> (Archived by WebCite at <http://www.webcitation.org/6QYyjhP7>).

KEYWORDS

Parkinson disease; ballroom dancing; balance; posture

Introduction

Parkinson disease (PD) is a common, progressive neurological condition estimated to affect 100-180/100,000 of the population [1]. People with this condition frequently experience deterioration of their spinal posture, mobility, and stability, leading to dependency and falls; therefore, preventing the cycle of inactivity and secondary complications is a priority. Despite disabling movement deficits, access to physiotherapy is limited [2]. Poor performance on measures of balance and functional tasks is common and has been associated with generalized deficits of attention and fall events, leading to decreased quality of life among sufferers [3]. The problem of unwanted secondary deterioration is of considerable concern.

People with PD experience slow movements (bradykinesia), rigidity, resting tremors, and abnormalities of postural reflexes. Gait characteristics include a shuffling pattern of walking with increased flexion of the hips and thoracic spine and reduced movement at the ankle with loss of heel strike. Restricted rotational movements of the head and trunk can contribute to the overall instability experienced by individuals. Key approaches to improving the function and activity of people with PD include balance and strengthening exercises [4] as well as strategies using rhythmical cueing to enable people to initiate movements [5]. Ballroom dancing comprises many of these facilitating components described; hence, the reason that dance was considered an appropriate activity for people with PD. The music provides the rhythmical cue for stimulating movement and the stepping and turning activities challenge balance control.

Self-help and physical leisure activities are increasingly important in the battle to maintain safe functional mobility among people with PD. Although there is growing evidence of the benefits of exercise for people with PD, research into the benefits of long-term exercises through leisure pursuits such as dance and self-help activities is limited. Research has shown that people with PD are interested in dance and early findings suggest a positive effect on balance and gait following Argentine tango classes, partnered or nonpartnered [6]. The effectiveness literature on dance in PD is growing, although the findings of the early studies have been limited by small sample sizes—the average study recruiting under 20 participants, and the largest recruited 52. These studies have shown proof of principle that dance, usually Argentine tango, for people with PD can be delivered [6-12] and can positively influence balance control and gait. Another study compared the tango with the waltz and the foxtrot and dance was superior to no dance but there was no distinction among dances. One-hour sessions, twice weekly for 10 weeks is beneficial. Only one recently completed study has evaluated dance delivered in the community. Earhart and Duncan [13] and Foster and Earhart [14] described a 12-month community-based tango program that demonstrated that dancing using community facilities was possible and they showed that those participants who danced increased their participation in

activities of daily living. Positive effects were also shown when people were tested off medication.

Gaps in knowledge have been highlighted by a number of researchers. Two meta-analyses have identified the need for more well-designed randomized controlled trials and qualitative studies of the dance experience of people with PD [15,16]. Hackney and Earhart [6] highlighted a gap of knowledge concerning the long-term effects and cost effectiveness of dance. No existing studies have examined the influence of dance on spinal posture and turning (a task that inherently makes people unstable) or the personal insights of participants about their experiences with dance. We were aware that no-one had examined the feasibility of teaching a number of standard ballroom dances to people with PD through a local dance center in the UK or how a center would cope with finding dance partners for people with PD, and it is important to explore these feasibility issues before running a large multicenter trial.

Because this is a feasibility study, we will not be testing a hypothesis but will determine the methodological feasibility of evaluating the benefits of multiple dances taught through a dance center as a precursor to a definitive phase III trial. We need to understand how much dance people with PD and healthy partners will tolerate, which dances work best, how easy it is for dance teachers and dance centers to accommodate the needs of people with PD, and identify barriers and facilitators to participation in dance including the financial costs. We will build on the proof of principle studies [6-8] from the United States, address gaps in knowledge in planning a definitive trial of the impact of dance on balance and spinal posture, as well as turning, long-term follow up, economic evaluation, and user views. We will examine the appropriateness of primary and secondary outcomes currently envisaged for the future main trial and provide novel insight into user views on involvement in dance through a qualitative component, and develop procedures for economic evaluation for a future trial.

Specific questions of the feasibility study are:

1. What are the key routes to successful recruitment of healthy partners, people with PD, and dance centers to a randomized controlled trial of dance?
2. What are the most appropriate dances for people with PD?
3. How frequent, and how much dance is reasonable and likely to result in benefit for people with PD and healthy partners?
4. What specific adjustments do dance centers need to make regarding the delivery of dance to this group of people?
5. What level of dancing will be sustained to 3 and 6 months?
6. Will we obtain high quality data on spinal posture, balance, turning, and walking during home assessments?
7. Will we obtain high quality data on self-reported health status and balance confidence?

8. How appropriate and burdensome is the battery of assessments?

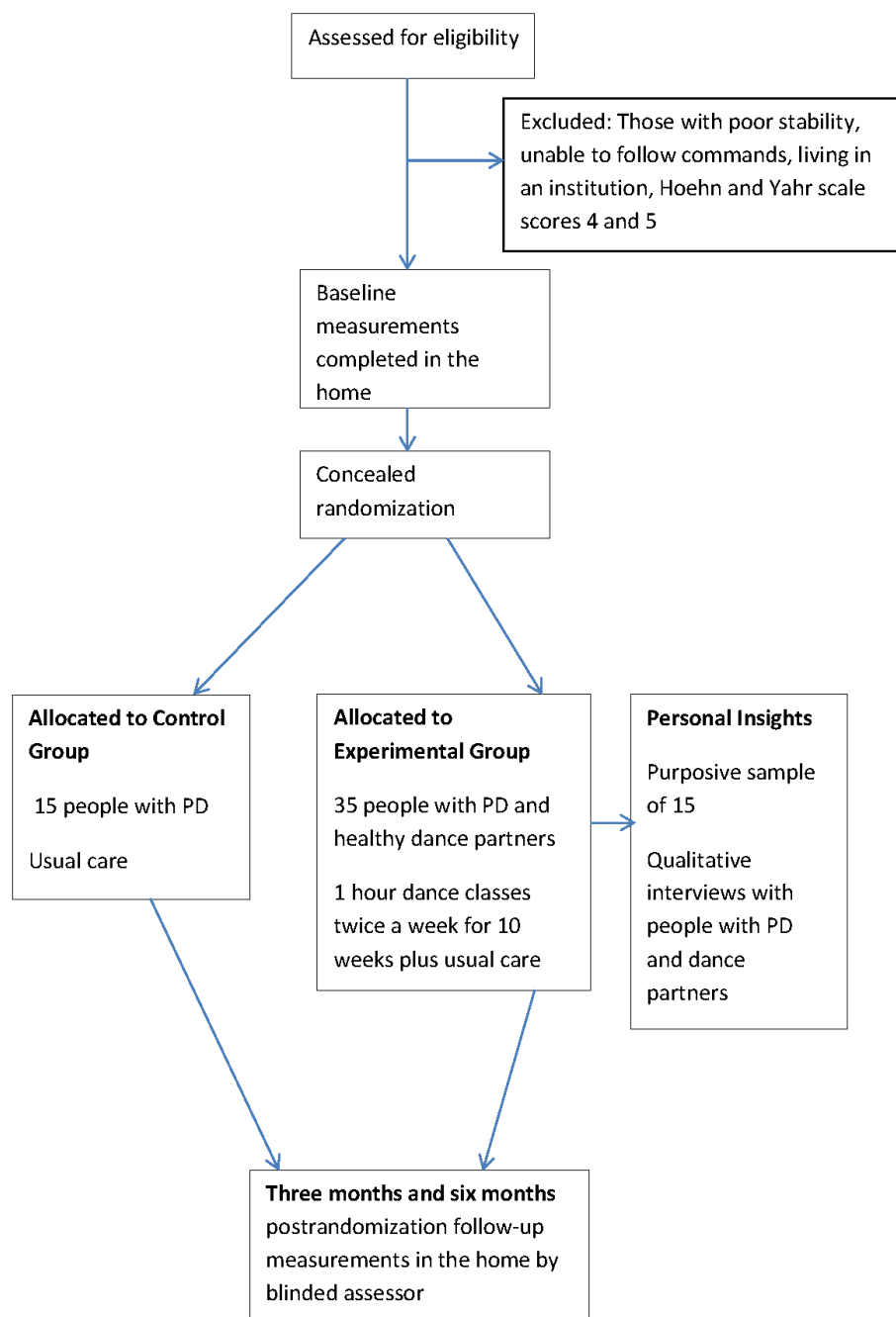
Trials (CONSORT) [18] flowchart. Two research fellows, physiotherapists with experience in PD, will conduct the research trial in collaboration with the dance teachers in a dance center in the South of England. Research fellow A will recruit participants and conduct baseline and follow-up assessments and will be blind to group allocation. Once a participant has consented to the trial, their name will be passed on to the second research fellow B, who will carry out the random allocation procedures, be present throughout all the dance classes, help arrange transport to the dance classes according to need, and organize volunteers for dance partners.

Methods

Overview

We followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [17] for developing the protocol and Figure 1 presents a diagrammatic representation of the study based on the Consolidated Standards of Reporting

Figure 1. Flowchart of trial design.



Participants With Parkinson Disease

Research fellow A will obtain informed consent and recruit 50 people with PD from outpatient services, local support groups (Parkinson's UK), and the DeNDRoN (Dementia and Neurodegenerative Disease Research Network, a clinical research network for dementia and neurodegenerative conditions). Eligible people with PD will have a confirmed diagnosis of PD, Hoehn and Yahr [19] scale of 1-3 indicating mild-to-moderate mobility and stability; will be able to stand, turn, and walk safely and unsupported but may experience freezing of gait [20]; will live at home; understand and follow commands, through a screen for cognitive impairment [21]; and be able to tolerate the dance intervention. People with PD lacking sufficient stability to dance with another person in the clinical opinion of research fellow A (eg, in danger of losing balance control each time they turn around) will be excluded. The decision as to whether a potential participant with limited mobility can safely undertake the dance intervention will be based primarily on their performance on the Berg balance scale (BBS) [22] and the motor component of the unified Parkinson's disease rating score (UPDRS) [23]. For example, someone scoring 0 on questions 7, 8, or 13 of the BBS, indicating inability to "stand unsupported with feet together," inability "to attempt to reach forward" in standing without losing balance or inability "to stand unsupported with one foot in front of the other" will be considered ineligible. The UPDRS motor component gait questions 29 and 30 will also be used as indicators: a severe disturbance of gait that requires constant assistance or lack of postural stability to such an extent that balance is spontaneously lost in standing, will also discount potential participants.

Healthy Dance Partners

Healthy people identified by participants in the dance group will act as dance partners. Some people with PD will be single; others may have a spouse unwilling to participate, so relatives, volunteers, or responders to an advert will also be considered. The feasibility of recruiting healthy dance partners will be examined in the study. Our inclusion criteria for the dance partners are similar in age to people with PD, able to understand and follow commands, willing to participate, and able to tolerate the dance intervention. Evidence of a neurological condition, vestibular impairment, or multiple falls would lead to exclusion, but experience of a single fall would be acceptable (risk of falling is linked to repeated falling, not a single fall event) [24]. Otherwise healthy individuals who are considered to be at risk of instability while dancing will be excluded.

Randomization

After the baseline assessment, eligible and consenting people with PD will be randomized to the dance or control group.

Research fellow B obtained allocations by telephone from the trial medical statistician. Allocation will be randomized in 1 block of 11 participants (8 dance and 3 control), and 3 blocks of 13 (9 dance and 4 control), to yield participants entering each of 4 consecutive series of dance classes. The feasibility trial is too small to incorporate stratification. The dance-to-control ratio of 35:15 was chosen to maximize the number of people with PD experiencing the dance classes, while still including some control participants for feedback on the acceptability of randomization to control, retention, and fidelity in this group. The research fellow will contact participants to inform them of their allocation and of the times of their dance classes.

Interventions

Control Group

Participants in this group will continue with usual care. Usual care comprises medication, attendance at medical clinics, and review by PD nurses. Exercise therapy may be accessed but this is not routinely prescribed in the UK. As a way of encouraging adherence to follow-up at the end of the trial, participants in the control group will be offered vouchers to attend nontrial dance classes at the dance center.

Dance Group

In addition to usual care, participants will attend dance classes (with a healthy partner) at a local dance center, led by a professional dance teacher and supported by a second teacher and research fellow B (Figure 2). Classes will last 1 hour, twice a week for 10 weeks. The length and number of sessions was chosen following discussions with the dance teacher and based on results from published literature [6]. Care will be taken to ensure that the pace of teaching is appropriate and will reflect that recommended by Hackney and Earhart [6]. Class sizes will be small and supervision from both the dance teachers and research fellow B will minimize any risk of falling. Participants will learn 6 dances (3 ballroom and 3 Latin American dances). Each session will start with a warm-up, then new steps will be introduced and practiced, and a record of the session will be kept. Proposed dances included the social foxtrot, the waltz, the cha cha, ballroom tango, the rumba, and rock and roll. Emphasis will be placed on encouraging individuals to extend their postures, turn their heads and trunks, heel strikes, and toe push-offs because these movements are affected by PD and associated with changes in balance responses. The dance program will be tailored to individual capabilities in each class (the dance teachers will dance with couples who were struggling), and the research fellow will ensure the safety and well-being of participants and their partners. The research fellow will keep a record of each class, and some of the classes will be videotaped (with consent from participants).

Figure 2. Participants enjoying a dance class.

Assessments

Research fellow A will carry out baseline and follow-up assessments at 3 and 6 months and will be blinded to participant group allocation. Prior to each assessment, participants will be reminded not to reveal whether they have been dancing, and following each assessment the assessor will be asked to record awareness of group allocation. The assessments will be organized at similar times of the day, will last approximately 1 hour, and be completed in the person's home approximately mid-point in the medication cycle.

Data collected for the anticipated primary outcome measures for the main trial will be the BBS [22], a categorical scale of balance activities (a high score is good with a maximum of 56), and spinal posture, which will be measured using the spinal mouse [25]. The spinal mouse is a handheld device that can measure the position and mobility of the pelvis, and lumbar and thoracic spine by recording the segmental angles as it is rolled over the spine. This device has been used with people with PD [26] and the data will describe angles of the participants' spinal segments in the standing position and the overall degree of forward inclination in relation to upright. We used these tests in previous research studies [27].

At baseline, we will characterize our sample using the following measures: demographic data; measures of disease severity (Hoehn and Yahr Scale [19]; 1-5, high score is poor) and UPDRS motor section [23] (0-56, high score is poor); medication (using levodopa equivalent daily dose); freezing of gait questionnaire [20] (0-24, high score is poor); the Montreal cognitive assessment of cognitive function [21] (0-30, high

score is good); and we will ask participants to retrospectively recall fall events during the previous 12 months using a standardized questionnaire [28].

Outcome measures will be recorded at baseline, and at 3 and 6 months and included the primary outcome measures, the Berg balance scale [22] and the spinal mouse [25]. The secondary outcomes include a measure of turning, the standing start 180° (SS180°) test in which the individual turns in both directions and the number of steps, time, and quality of turn are rated [29]; the timed up and go test, stand up from a chair and walk forward 3 meters and turn and return [30]; the PDQ39 (a self-completing questionnaire rating how hard it is to complete a range of everyday activities [31]; 0-100, low score indicates better health); the ABC, which is a questionnaire about balance confidence [32] (0-100, high score is good); the phone-FITT, a questionnaire delivered over the phone and designed to gather information about levels of the physical activity of older adults, such as how many times a week do you do housework activities such as tidying or dusting, walking, swimming [33], scoring is according to frequency of activities, duration, and intensity; and the Euroqol-5D, which is a simple quality-of-life measure [34] (1-5, high score is poor but a high visual analogue score is good).

At the final assessment, participants will be given a questionnaire about resource use that will be used in economic evaluation such as travel, refreshments, and buying shoes for the dance class and their views on the acceptability and benefits of the research project and to collate additional information needed for the economic evaluation. Participants will be asked to complete this questionnaire on their own time and to return

it to the research team in the freepost envelope provided. We plan to ensure that the measurement battery is appropriate for use in a definitive multicenter phase III trial and not burdensome for the assessor or participants.

Statistical Analysis

Feasibility issues will be addressed by examining numbers and percentages successfully recruited and completing various components of the trial protocol. The choice of outcomes for the main trial will be addressed by examining the completeness of data collection, relevance to issues raised as important by users, and comparison to related studies in the literature. The statistical analysis plan for the primary efficacy outcome in the main trial is currently envisaged to contrast the dancing and control groups (presented with 95% CI), after controlling for the primary outcome measured at baseline and center, either performed separately at 3, 6, and 12 months in analysis of covariance, or in a mixed model including both follow-up points. Depending on the primary outcome chosen, the corresponding modelling approach in logistic or Poisson models may be appropriate. Comparisons of outcome will be done on an intention-to-treat basis, with sensitivity analyses restricted to those completing the allocated interventions. The analysis of outcome data from the pilot randomized controlled trial, along with information from the literature, will inform the power calculation for the main trial. The current trial is not powered to demonstrate efficacy. We will examine the predictive power of baseline characteristics such as the Hoehn and Yahr severity, freezing of gait, and phone-FITT scores, to assess the benefit of additionally including them as stratifiers in the randomization of the main trial.

Qualitative Substudy

Aim

The aim of the qualitative substudy will be to identify and explore the views of people with PD and their dance partners about the appropriateness and acceptability of the dance programs and the perceived impact on their mobility. Their views of the trial procedures will also be explored. An experienced qualitative researcher has been employed to complete this part of the study.

Methods

Fifteen of the 35 couples in the experimental group will be recruited to the qualitative study. Couples will be recruited with the aim of attaining maximum variation in the qualitative sample of the factors that may affect their experiences of the dance intervention, such as age, sex, and relationship with the dance partner.

Interviews

In-depth, semistructured, qualitative interviews will be conducted using an interview guide developed for the study. The interviews will be conducted in the home separately with the people with PD and their dance partners where possible (where couples are spouses this may not be possible) within 1 month of completing the dance program. With participants' consent, the interviews will be audiorecorded and fully transcribed. For people with PD, the interviews will explore the

following issues: their perceptions of the impact of PD on their day-to-day lives and their experience of physiotherapy or any other interventions since diagnosis that were designed to promote activity; and experiences with exercise activity (dance or other exercise activity) before their diagnosis of PD. The following issues will be explored with people with PD and their dance partners: their reasons for deciding to take part in the dance program and their perceptions and expectations of it, the number of sessions they attended and reasons for missing any sessions or dropping out, what it was like to take part, enjoyment of the activity, maintaining enthusiasm for the activity, the implications of working with a partner, perceptions of the impact of participating in the dance program, interest in continuing with dance classes or other activity, and their perceived impact on their mobility. Participants will also be asked about any personal costs they experienced while participating.

Analysis

Facilitated by QSR International's NVivo 9.2 software, the data will be managed using Framework [35] and analyzed thematically to explore participants' views about the acceptability and appropriateness of the dance program. Features of grounded theorizing and constant comparison will be used to identify and develop themes [36]. Data analysis will be undertaken by experienced social science qualitative researchers (JR and RW).

The framework is a staged approach that is well-suited to applied health research. In the first stage, the researchers will identify topics for an initial analytic framework based on prior understanding of the issues and concepts arising from close reading of the transcripts. In the second stage, participants' accounts will be condensed on a case-by-case basis into charts according to the framework topics. The third stage will involve working through the data in detail to draw out themes or categories of experience that capture the full range of perspectives identifying commonalities and differences within and between participants.

The qualitative findings will be used to inform interpretation of the findings of the trial. Analysis of the qualitative data will take part in isolation from the trial researchers. Data from the qualitative study will be integrated at the end of the trial to avoid contamination.

Finally we will explore the views of those who choose not to take part in the study. Typically it is viewed as unethical or unnecessary to ask people to give reasons for declining to take part in research; however, in this study the information that is handed out as part of the recruitment process will give people the option to tell us if and why they find the dance intervention unattractive by completing an anonymous short questionnaire.

Economic Evaluation Substudy

Aim

Our aim is to inform a future economic evaluation for the Phase III trial. We will use the EQ5D to assess quality of life.

Methods

A questionnaire about resource use such as travel, refreshments, and clothing (dance shoes) costs will be completed at 6 months. This information will enable us to judge the feasibility of this type of measure for people with PD. We will also calculate the resources needed to provide the intervention such as cost of dance lessons, hire of a hall, and personal expenditures.

Results

Recruitment began in January 2013 and the last participant is expected to complete the trial follow-up in June 2014.

Discussion

The main aim of this study is to determine the methodological feasibility of conducting a definitive phase III trial to evaluate the benefits of dance in people with PD. Recruitment to the feasibility trial began in January 2013 and the last participant is expected to complete their follow-up assessment in June 2014. Findings from our study will provide a novel insight into the way people with PD become involved in dance, their views and

opinions, and the suitability of our primary and secondary outcomes. We will report on the challenges of recruiting healthy dance partners as well as people with PD, and because we believe the dance partnership is key to the success of the dance experience, we look forward to understanding better the ingredients required for success. We suspect that threats to the viability of the feasibility trial are likely to come from poor recruitment of healthy partners to dance with people with PD, demands and difficulties related to traveling to the dance center, and reluctance of people with PD to dance twice a week for 10 weeks. We anticipate that ease of travel and access to facilities such as the availability of car parking and taxis as well as environmental hazards will affect the experience. We will consider the steps that need to be taken to ensure safety and we are keen to analyze the types of dances that are enjoyed and those that create challenges for people with PD. We look forward to evaluating the potential benefits and challenges of running the dance classes for people with PD as well as providing practical information, such as participants' preferences and experiences of the different dances, which has not previously been reported. With this study, we will be well placed to inform future research in this field.

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Conflicts of Interest

None declared.

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Abbreviations

BBS: Berg balance scale

CONSORT: Consolidated Standards of Reporting Trials

PD: Parkinson disease

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

UPDRS: unified Parkinson's disease rating score

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Protocol

Diet, Physical Activity, Lifestyle Behaviors, and Prevalence of Childhood Obesity in Irish Children: The Cork Children's Lifestyle Study Protocol

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Abstract

Background: Childhood obesity is complex, and its aetiology is known to be multifaceted. The contribution of lifestyle behaviors, including poor diet and physical inactivity, to obesity remains unclear. Due to the current high prevalence, childhood obesity is an urgent public health priority requiring current and reliable data to further understand its aetiology.

Objective: The objective of this study is to explore the individual, family, and environmental factors associated with childhood overweight and obesity, with a specific focus on diet and physical activity. A secondary objective of the study is to determine the average salt intake and distribution of blood pressure in Irish children.

Methods: A cross-sectional survey was conducted of children 8-11 years old in primary schools in Cork, Ireland. Urban schools were selected using a probability proportionate to size sampling strategy, and a complete sample of rural schools from one area in Cork County were invited to participate. Information collected included physical measurement data (anthropometric measurements, blood pressure), early morning spot and 24 hour urine samples, a 3 day estimated food diary, and 7 days of accelerometer data. Principal- (school head) reported, parent/guardian-reported, and child-reported questionnaires collected information on lifestyle behaviors and environmental attributes. The Cork Children's Lifestyle Study (CCLaS) was designed by the Department of Epidemiology and Public Health in University College Cork, Ireland in 2011 and 2012. Piloting and modification of study methods was undertaken. Data collection took place between April 2012 and June 2013.

Results: Overall, 27/46 schools and 1075/1641 children, of which 623 were boys, participated. Preliminary data analysis is underway. It is anticipated that the results of the CCLaS study will be available in late 2014.

Conclusions: The CCLaS study has collected in-depth data on a wide range of individual, family, social, and environmental correlates which will allow us to access multilevel influences on childhood obesity. This study will contribute to the evidence base by highlighting current knowledge and gaps regarding the predominant drivers of childhood obesity.

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KEYWORDS

overweight; obesity; children; diet; physical activity; lifestyle; Ireland

Introduction

Childhood Obesity, Extent of the Problem

The worldwide prevalence of childhood obesity has increased significantly over the past three decades, particularly in North America and Western Europe [1,2]. Currently, over one in four Irish children are overweight or obese, and similar estimates are found in many other developed countries [1,3]. Childhood obesity can affect not only current health, but health in later life as well, and is a risk factor for metabolic syndrome, cardiovascular disease, and type 2 diabetes mellitus [4-7]. With the high prevalence and known adverse consequences of being obese [8,9], childhood obesity remains an urgent public health priority requiring current, detailed, and reliable data to further understand its aetiology, and to inform public health policies and interventions [10,11].

Environmental and Lifestyle Factors

Obesity is a complex problem [12], and occurs as a result of a persistent positive energy balance where energy intake is greater than energy output [13]. Social ecological theory suggests that multiple levels of influence including individual, family, community, and organizational factors can enable or constrain health related behaviors that should to be considered when researching the determinants of obesity [14]. There is increasing consensus that environmental and lifestyle factors, rather than genetic or biological factors, are the primary drivers of the current childhood obesity epidemic [15-18]. A number of likely determinants of obesity have been identified including poor diet, physical inactivity, sedentary behavior, low socioeconomic status, and the built neighborhood environment [19-24].

There is a general perception that poor diet and physical inactivity are major contributors to the current obesity epidemic [25]. However, the relative contribution of poor diet and physical inactivity to childhood obesity are not well understood [26-29]. For example, little is known about dietary behaviors including food choice [30] and salt intake in children [31]. High salt intake is associated with poor diet [32,33], high blood pressure (BP) [34], and increased energy intake in children [35]. However, the association between childhood obesity and salt remains understudied, with some research indicating that salt may be indirectly associated with obesity through poor dietary choices including sugar sweetened beverage intake [35]. This is of concern as dietary behaviors [36] are established at an early age, and both obesity and BP track throughout one's life [9,37].

The complex interplay between lifestyle patterns and environmental factors further complicates uncovering pathways to obesity [38]. Studies containing in-depth data on the association between a broad range of lifestyle factors and multiple measures of weight status are sparse, particularly in the Republic of Ireland. A small number of Irish studies have assessed diet, physical activity, or weight status in children, but most have only collected data on either physical activity or diet. In addition, most have used self-reported measures of weight status or physical activity, and little evidence is available on the wider environmental determinants of lifestyle patterns and obesity [39-41]. As the Cork Children's Lifestyle Study (CCLaS) collected in-depth data on diet, physical activity, and

weight status, this provides a unique opportunity to gain a deeper understanding on the multilevel influences associated with childhood obesity in Ireland.

The CCLaS study aims to estimate the current prevalence of obesity in Irish children, and to explore determinants of childhood obesity at an individual, family, and environmental level, with a specific focus on dietary patterns and physical activity. The secondary aim of the CCLaS study is to estimate average salt intake and examine BP distribution in Irish children.

Methods

Aims and Objectives

The CCLaS study aims to assess the current prevalence of overweight and obesity in Irish children, and explore risk factors at an individual, family, and environmental level in a sample of children 8-11 years of age in primary schools in Cork, Ireland.

Primary Objectives

A primary objective is to assess the weight status and estimate the current prevalence of overweight and obesity using objectively measured height, weight, waist circumference, and skinfold thickness measurements in Irish children 8-11 years of age.

Another primary objective is to explore individual, family, and environmental factors associated with childhood overweight and obesity, with a specific focus on dietary patterns and objectively measured physical activity.

Secondary Objectives

A secondary objective is to assess the average salt intake and distribution of BP in children 8-11 years old in Ireland.

Study Population

The CCLaS study is a cross-sectional survey conducted in Cork, Ireland. Cork is located in the South West of Ireland, and Cork City has a population of 120,000. Mitchelstown is a rural area in Cork County with a population of >3000, and is located approximately 50 kilometers from Cork City. Information on primary schools in Cork City and Mitchelstown was obtained from the Department of Education and Skills website [42]. The website contains information on school name, location, gender mix, size, and disadvantaged status. Disadvantaged status is assigned to schools based on the sociodemographic and socioeconomic profile of the families whose children attend the school [42]. At the national level, one in five primary schools has disadvantaged status. However, nearly half of Cork City schools have disadvantaged status, with approximately 40% of primary school children in Cork City attending a disadvantaged school [42].

Special needs schools and schools without age eligible children were excluded from the sampling frame. All other primary schools in Cork City and Mitchelstown were included in the sampling frame. At the time of sampling, there were 51 primary schools with approximately 13,230 students in Cork City which met the sampling frame criteria. All 5 primary schools in Mitchelstown (with approximately 800 students) met the sampling frame criteria [42]. Children in 3rd and 4th classes

(years 5 of 6 of enrollment into primary school) were the target population, as we wished to recruit children of a similar age to previously conducted Irish research [39].

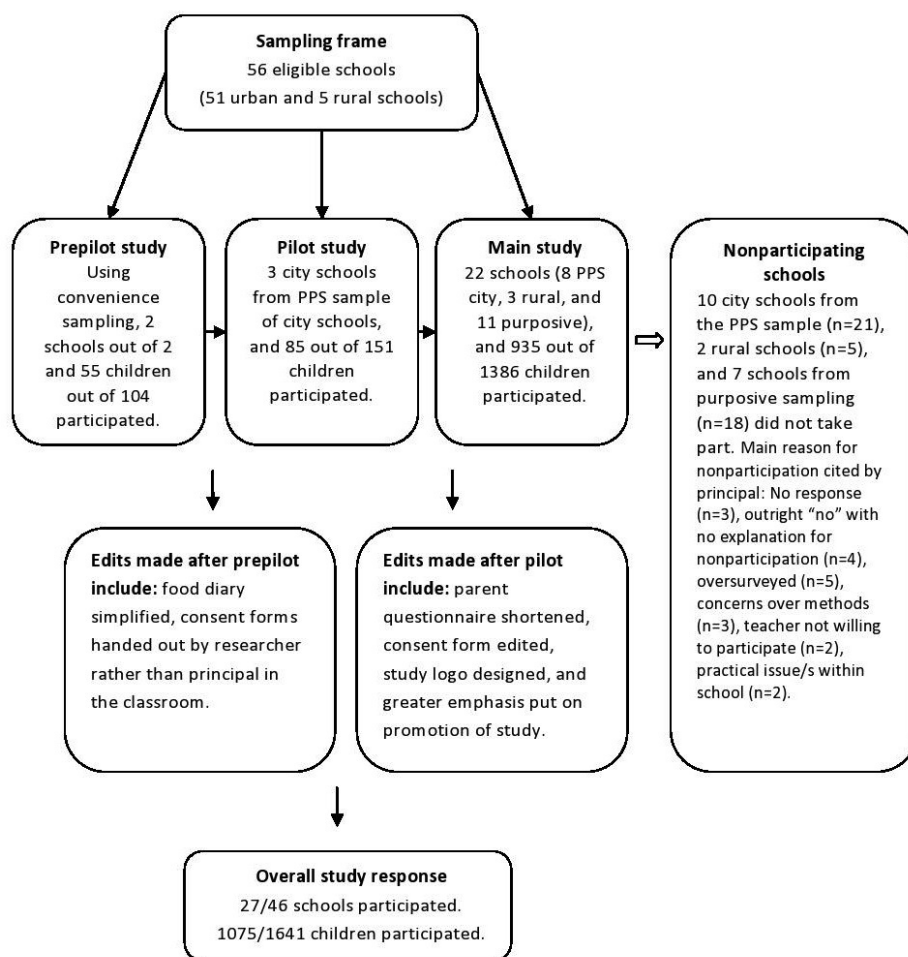
Sampling Method and Sample Size

The study aimed to recruit 1000 participants in order to estimate the prevalence of overweight and obesity in Irish children with a precision of $\pm 2.7\%$, assuming a 26% prevalence rate of overweight and obesity within the study sample [43]. Allowing for a response rate of 70%, it was estimated that 1500 participants would need to be invited to partake in the study.

For the prepilot study, 2 city schools were recruited using convenience sampling. For the pilot and main study, a probability proportionate to size (PPS) sampling strategy was used to select a random sample of primary schools in Cork City.

The PPS sample of city schools was based on school size. A small school was defined as having <100 pupils, a medium school having 100-300 pupils, and a large school having >300 pupils. A complete sample of schools in Mitchelstown was invited to participate in the study. In order to achieve the sample size requirements, the schools not willing to participate in Cork City were replaced using a further purposive sampling strategy. The schools not willing to participate were replaced to represent the sampling frame population for: (1) school disadvantaged status, and (2) gender. As the recruitment of schools was undertaken over two consecutive school years, schools were sampled without replacement. All children in 3rd and 4th classes of participating primary schools were invited to participate in the study. Figure 1 shows a summary of the sampling and recruitment process.

Figure 1. Flowchart of sampling and recruitment of schools and children in the Cork Children's Lifestyle Study. PPS=probability proportionate to size.



School and Participant Recruitment

The principals (school heads) of selected schools were sent an invitation letter, an information sheet, and a presentation containing study details. The principal was then contacted by telephone to arrange a face-to-face appointment with a study researcher to discuss the study. During the study meeting with the principal, the study aims, proposed methods, and study procedures were discussed. With the principals' permission, the research team introduced the study to the 3rd and 4th class

children of participating schools, and a parent/guardian information letter and consent form was given to each child to bring home. The children were advised to discuss the study with their parents/guardians, and to return the consent form to the school if they and their parents/guardians were willing to participate. The parent/guardian consent form was divided into 3 sections. The first section gave permission for the study child to participate in the study. The second section gave permission for a urine sample to be provided by the study child, and the

third section gave permission for the urine sample to be stored by long term freezing.

Data Collection Methods

Testing/Piloting

Prior to the main study, a prepilot study was conducted in two Cork City primary schools in April-May 2012, and a pilot study in 3 Cork City primary schools in May-June 2012. Overall, one hundred and forty children from 2 mixed gender schools, two boys' schools, and one girls' school were recruited to participate. The study piloting aimed to test practical research issues including the timing of procedures. The study methods and study documents including the food diary and questionnaires were also tested and assessed during piloting. Study documents, the study protocol, and standard operating procedures (SOP) were amended where necessary. Modified versions of the study documents are available from the lead author on request.

Schools and Classroom Procedures

The study researchers were advised to strictly adhere to the methods outlined in the study protocol and SOP during the fieldwork process. Within the classroom, each child was provided with a study pack which contained: (1) a child questionnaire, (2) a parent/guardian questionnaire, (3) a 3 day estimated food diary, (4) an accelerometer and instructions, and (5) a urine collection cup and instructions (where parent/guardian consent was granted). The research assistants were present for all classroom procedures and offered support and assistance where necessary. The children completed a self-reported questionnaire within the classroom, which was checked for completeness while on site. The accelerometers were described and placed on the nondominant wrist of each child. The 3 day estimated food diary was explained using a poster template of the food diary. The researchers explained how to fill in the food diary, and with assistance, that morning's breakfast was completed by the children within the classroom. The children were informed how and what day to provide the urine sample, which was to be returned to the school once complete. The children were also instructed to return the parent/guardian questionnaire to the school once complete. A "pictogram" poster was placed in the classroom to remind children of the of study details they needed to recall.

Questionnaire Data

[Multimedia Appendix 5](#) outlines the individual, family, and environmental factors measured in each questionnaire (see [Multimedia Appendices 1-3](#), and [5](#) for questionnaires and outline of factors). The questionnaires were developed based on previously tested and validated questions, with modification of some questions for the purposes of this study. Details of each questionnaire are described below.

Principal Questionnaire

The principal of each participating school was asked to complete a questionnaire which included questions under 6 main headings: (1) demographics, (2) health curriculum, (3) school policy environment, (4) level of nutritional care, (5) provision of physical activity, and (6) parental/community support. This

questionnaire has been used previously in a cross-sectional study in schools in Cork City [44].

Child Questionnaire

The child questionnaire was developed using questions from the following sources: (1) Sport, Physical Activity and Eating Behavior: Environmental Determinants in Young People study [27], (2) Growing Up in Ireland (GUI) study [39], (3) Growing Up in Australia: The Longitudinal Study of Australian Children (LSAC) [45], (4) Child Heart and Health Study in England [46], and (5) Physical Activity for Older Children Questionnaire [47].

The child-reported questionnaire contained questions under 5 major headings: (1) background information, (2) your neighborhood, (3) food and diet, (4) sports and physical activity, and (5) hobbies and activities.

Parent/Guardian Questionnaire

The parent/guardian questionnaire was developed using questions from a number of sources: (1) GUI study [39], (2) Survey of Lifestyle, Attitudes, and Nutrition in Ireland [48], (3) Avon Longitudinal Study of Parents and Children [49], (4) LSAC study [45], (5) National Survey of Children's Dental Health [50], (6) Eating Among Teens Survey 1 [51], (7) Mitchelstown Cohort study [52], (8) Irish Census [53], (9) Child Feeding Questionnaire [54], (10) short version (self-administered) of the International Physical Activity Questionnaire [55], and (11) Warwick-Edinburgh Mental Well-being Scale [56].

The parent/guardian-reported questionnaire contained questions under 9 major headings: (1) study child's birth factors, (2) study child's current health, (3) study child's exercise and physical activity, (4) study child's hobbies and activities, (5) study child's diet and dietary habits, (6) current parental health, (7) parental diet, (8) general family eating questions, and (9) family background.

Dietary Intake

Dietary intake was assessed using a consecutive 3 day estimated food diary which was developed for the purposes of this study (see [Multimedia Appendix 4](#) for template of food diary). Instructions to complete the food diary, including food atlas photographs [57] to aid portion size estimation, were located at the beginning of the food diary. Each day in the food diary was broken into six meal sections. Each meal section had a preassigned title: (1) breakfast, (2) morning snack, (3) lunch, (4) afternoon snack, (5) dinner, and (6) evening snack. There were six key questions to answer within each meal section: (1) time meal/snack was consumed, (2) location meal was consumed, (3) type of food or drink consumed, (4) quantity of food or drink consumed, (5) quantity leftover, and (6) cooking method used. The food diary was explained to the children in the classroom setting. First, the layout of the food diary was explained. Using a poster template, the children were shown how to fill in each meal section. The children were also shown how to use the food atlas photographs at the beginning of their food diary to help estimate portion size.

Once the food diary was explained in the classroom, the children were asked to fill in what they had for breakfast that morning.

A member of the research team spent some time with each child to ensure that they understood what was involved. The children were advised to seek help from parents and teachers when filling in their food diary where possible. Detailed debriefing with the children occurred after the 3 day period using a prompt sheet and food atlas [57] in order to ensure completeness. Where necessary, additional information was sought from the children, especially where food or drink items were not recorded in detail. Food diary data will be analyzed using WISP version 4 (Tinuviel Software, Anglesey, UK). Output measures will include nutrient intake, individual food intake, and food group intake.

Physical Activity

Free living physical activity was measured over a consecutive 7 day period using a validated tri-axial GENEActiv accelerometer [58,59]. The GENEActiv accelerometer is a small, light weight, waterproof device [60]. The manufacturer (Activinsights Limited) calibrated the units prior to the study commencing. The accelerometers were set to record data at 100Hz for 7 days using the “on button press” setting on the GENEActiv software version 2.2. The children were asked to wear the accelerometer all day and night over the 7 day period. They were informed only to remove the accelerometer for sports if their coach suggested it was necessary. The accelerometers were fitted on the wrist of the nondominant hand, and information on handedness was recorded by the research assistants. The accelerometers were downloaded in “.csv” and “.bin” format, and saved on hard drives. The data will be collapsed into 1 second and 1 minute epochs for data analysis.

Output measures will include sedentary time, low, moderate, and vigorous activity. The classification thresholds for activity intensity will be defined using those outlined by Phillips et al, which were designed specifically for the GENEActiv accelerometer [59].

Anthropometric and Blood Pressure Measurements

The anthropometric and BP measurements were taken by fully trained researchers using standard procedures. The researchers received training from an experienced research nurse and dietician prior to the study commencing. Retraining sessions occurred during the data collection period to ensure standard procedures were being employed during measurements. The data was also checked for measurement variability during the data collection period. The study equipment was calibrated prior to data collection, and monthly thereafter.

A summary of the anthropometric and BP measurements methods is described in Table 1. All measurements were taken in a sensitive manner in a private room or behind screens in each primary school. There were two children and at least two research assistants that remained in the room at all times. For the waist circumference and skinfold thickness measurements where two readings were taken, the mean value will be used for analysis. The children will be classified as normal weight, overweight, or obese using age and gender specific International Obesity Taskforce cut off points [61]. Mean systolic and diastolic BP will be calculated using the average of readings two and three.

Table 1. Summary of study methods.

Measure	Number of measures	Device	Method
Height	1	Leicester portable height stick	Measured to the nearest mm without shoes.
Weight	1	Tanita WB100MA mechanical scales	Measured to the nearest 0.1 kg without shoes and in light clothing.
Waist circumference	2	Nonstretch tape Seca 200 measuring tape	Measured to the nearest mm and located at the midpoint between the child's lower rib margin line and the iliac crest.
Skinfold thickness (triceps)	2	Holtain Tanner/ Whitehouse skinfold calipers	Measured at the right hand side of the body to the last complete mm. The triceps was located on the posterior midline of the upper arm, over the triceps muscle, halfway between the acrosion process and olecranon process. The elbow was extended and relaxed for the measures.
Skinfold thickness (subscapular)	2	Holtain Tanner/ Whitehouse skinfold calipers	Measured at the right hand side of the body to the last complete mm. The subscapular was located on the diagonal line coming from the vertebral border to between 1 and 2 cm from the inferior angle of the scapulae.
Mid upper arm circumference	1	Nonstretch tape	Measured using a nonstretch tape to the nearest mm from the right arm while relaxed. The midpoint was located half ways between the top of the shoulder and the tip of the elbow.
BP	3	Omron M6	BP was measured from the right arm using a validated automatic oscillometric device [62,63]. The mid upper arm circumference determined cuff size. The cuff was placed approximately 2 cm above the crease of the elbow. The child was seated comfortably for at least 5 minutes prior to the first reading. BP was measured three times, with one minute between each measurement. Children were asked to remain quiet and to sit still while each reading was being taken. Systolic BP, diastolic BP, and pulse were recorded.
Accelerometer	7 consecutive days	GENEActiv	Accelerometers were set to record data at 100 Hz and was worn on nondominant hand for 7 days.
Estimated food diary	3 consecutive days		Children recorded everything they ate and drank for 3 days. Food diaries were fully debriefed by a trained researcher after the 3 day period.
Early morning spot urine sample	1		Children were asked to provide an early morning spot sample on a day, which corresponded to a food diary completion day.
24 hour urine sample	1		A subsample of children were asked to provide a 24 hour urine sample on a weekend day, which corresponded to a food diary completion day.

Urine Samples

Only children whose parents provided consent for urine collection were provided with a urine collection cup and instructions. The children were asked to provide an early morning spot urine sample on a specified day, which corresponded to a food diary completion day. Where principals were agreeable, a subsample of children were asked to provide a 24 hour urine sample (n=100) on a weekend day, which corresponded to a food diary completion day. There were sixteen children from one of the prepilot schools that were asked to provide an early morning spot and 24 hour sample. The 24 hour samples provide an indication of average urine volume produced in a 24 hour period by the children. Osmolality testing was carried out on the 24 urine samples to determine urine concentration using a Micro-Osmometer Model 3300 in Cork University Hospital, Cork, Ireland. The hydration status of the children with 24 hour samples will be determined from the osmolality derived urine concentrations. All samples were

analyzed for sodium, potassium, urea, and creatinine in the Biochemistry Department in the Mercy University Hospital, Cork, Ireland (Accredited Laboratory ISO-15189). All electrolytes were analyzed using the Abbott Architect c8000 (Abbott Laboratories). The methodology for sodium and potassium measurement used ion-selective electrodes, urea analysis was based on an enzymatic assay using urease, and creatinine was analyzed using the kinetic alkaline picrate method. Where consent was provided, a 2 ml aliquot urine sample was frozen in a secure, password protected freezer.

Ethics and Ethical Issues

Ethical approval for the CCLaS study was obtained from the Clinical Research Ethics committee of the Cork Teaching Hospitals, Cork, Ireland. Only children with parent/guardian informed consent participated in the study, and parents/guardians were free to withdraw their children from the study at any point. Feedback on the physical measurements was provided to all parents of participating children in the form of a letter. The

parents of children with high BP or morbid obesity were advised to consult their general practitioner, and a general practitioner letter was enclosed with the feedback. A consultant pediatrician and a consultant in general internal medicine and nephrology from the Mercy University Hospital, Cork, Ireland provided advice on any high or unusual readings prior to feedback being provided to parents.

Data Processing and Quality Assurance

Comprehensive data cleaning was undertaken. First, all data were checked for outliers. There was 10.04% (108/1075) of the data that was then randomly selected and rechecked for errors. Out of the 39,999 questionnaire data points checked, 139 errors were found and corrected. An error rate was then calculated (0.35% for questionnaire data). Missing data will be accounted for during data analysis either by data imputation or by creating missing data categories. Imbalances in the study sample will be accounted for using sampling weights. A standardized codebook will be generated to ensure standard definitions and cut off points are used during analysis.

Analysis Plan

The data will be analyzed using the statistical software package Stata 12 IC (StataCorp LP). All necessary statistical assumptions will be tested prior to data analysis. Basic descriptive statistics will be used to describe the study population, and will provide prevalence estimates of overweight and obesity. Basic descriptive statistics will also be used to explore BP distribution. Descriptive findings will be stratified by gender. Crude and adjusted multivariate analysis will be conducted to assess the association between outcome variables and possible determinants. A multilevel approach will be adopted to examine obesity and possible group level determinants (individual, family, and environment). Latent class analysis will be conducted to identify subtypes of Irish children with respect to their diet, physical activity, lifestyle choices, and obesity risk.

Results

Data collection was undertaken between April 2012 and June 2013. Preliminary data analysis is underway. It is anticipated that the results of the CCLaS study will be available in late 2014.

Discussion

Lessons Learned During the Pilot Studies

The pilot studies provided valuable insight into a number of practical and methodological issues. The practical and operational issues encountered included timing, obtaining an adequate response rate, and increasing awareness of the study in the local community. Obtaining a principal's consent for a school to take part in the study took longer than anticipated, especially when teachers, board of management committees, and parent associations were consulted. In the main study, greater lengths of time were allowed when approaching schools to participate in the study. A relatively low response rate from parents and children was obtained during the piloting phase of the study. A possible explanation for this is that the piloting

phase of the study was undertaken close to the summer holidays. However, for the main study a number of methods were used to encourage a greater response rate. The children were given a longer period of time to return the consent forms, a study logo was designed, and researchers wore study t-shirts with the logo when introducing the study in order to be more child friendly. Numerous phases of promotion of the study were also undertaken, with articles being written in local newspapers and letters being sent to local health and community organizations promoting the study. Study posters were also placed in shops and businesses throughout Cork City and Mitchelstown.

Methodological issues were also encountered, especially in terms of study document design. The original consent form was too complicated, and as a result was not being completed correctly by parents. In some cases it was difficult to decide if a parent was providing consent or not. Therefore, the consent form was made clearer and easier to complete. The parent questionnaire appeared to be too long, and this may have acted as a disincentive for parents to complete later sections in the questionnaire. For the main study, a number of questions were removed, and the questions of utmost importance were located at the start of the questionnaire. On the cover page of the questionnaire, parents were informed of the aim of the questionnaire and of the anticipated length of time needed to complete all of the questions. The food diary used in the pilot study was too complicated for children 8-11 years old to understand and fill in completely. As a result, this made the debrief process difficult. The food diary was made more child-friendly by changing the layout, reducing the number of questions asked about each meal, and by including a number of photographs from the food atlas [57] at the beginning of the food diary to aid portion size estimation.

Recruitment Issues

Recruitment from schools is a difficult, multilevel process involving principals, teachers, parents, and their children [64]. Some research suggests that recruiting schools to participate in studies is becoming increasingly difficult, with nonresponse within schools becoming increasingly evident [65-67]. The CCLaS study aimed to collect data from a predominantly urban location (Cork City) and from one rural location (Mitchelstown). It was intended that an equal proportion of girls and boys would be recruited, and that the proportion of children attending disadvantaged versus nondisadvantaged schools would represent the sampling frame. During the study, recruitment of schools proved difficult, and further purposive sampling was necessary to achieve sample size requirements. A greater proportion of boys participated, and this is likely due to the nature of the study methods used. Boys only schools appeared to be more interested than girls only schools in the physical activity and accelerometer aspects of the study, and were interested to participate for this reason. On the contrary, the principals of nonparticipating girls only schools appeared more concerned about the anthropometric aspect of the study, and some principals expressed concerns over the sensitivity and possible long-term implications of measuring children.

Disadvantaged schools were more difficult to recruit than nondisadvantaged schools. Some school principals expressed

concerns over the study methods, especially regarding children providing a urine sample. There were three principals from disadvantaged schools that agreed to take part in the study only on the condition that urine samples were not collected from the children in their school. School principals reported a variety of other reasons for not partaking. These include the low literacy of parents whose children attend the school, parents being suspicious of the study or study methods, the school being too busy, and other schools gave an outright “no” with no explanation for nonparticipation. Research fatigue in Cork City schools was also evident, with a number of nonparticipating schools reporting they had just taken part in a different study or found studies overly time consuming. The proximity of city schools to local research institutions is a likely explanation for research fatigue, and thus, further school based studies require carefully designed recruitment strategies.

Strengths

The sample size is relatively large, and represents 1075 children out of approximately 3350 eligible children in the overall sampling frame. A predominant strength of this study is the depth of data on lifestyle, diet, and physical activity data collected at an individual, family, and school level which will allow for in-depth exploration on the potential determinants of childhood overweight and obesity. This is one of the first studies in Europe designed to collect such data. A number of objective anthropometric measurements were taken to describe weight status. The study collected objectively measured physical activity data in free living conditions over a 7 day period. The corresponding physical activity questionnaire data will provide valuable information of the context of physical activity behaviors and patterns. Seasonality will be accounted for, as the data was collected throughout the school year (October-June). The thoroughly debriefed 3 day estimated food diaries provide comprehensive data on dietary intake patterns and behaviors. This is the first study, to our knowledge, in Ireland to provide objective estimates of salt intake from spot and 24 hour urine samples, and to assess the distribution of BP in a large sample of Irish children.

Limitations

There are a number of limitations to the study. A relatively low response rate was obtained from the original sample of city schools, though the desired sample size was achieved using purposive sampling. However, some response bias may have been introduced into the study. Information on nonresponding children is not available. As the food dairies are self-reported, some misreporting and nonreporting may have occurred. However, the food diaries were thoroughly debriefed by a trained researcher, though this may have resulted in some reporting bias of dietary intake. A 3 day food diary may not be representative of habitual dietary intake. Some response bias may have been introduced into the child questionnaire responses, as they were completed in a classroom setting, though children were encouraged to complete the questionnaires independently. As this study is cross-sectional in nature, no causal inference can be implied.

Conclusions

This study aims to estimate the current prevalence of overweight and obesity in 8-11 year old Irish children. The research from the CCLaS study will explore the individual, family, and environmental correlates of childhood obesity, and will identify clusters of Irish children in relation to their dietary and physical activity patterns and lifestyle choices. The distribution and determinants of children’s salt intake and BP will also be analyzed as part of this study. To date, there are no reliable data on the average salt intake or distribution of BP in Irish children. Valuable comparisons with findings at an Irish, European, and International level will be made. In particular, CCLaS study findings will be compared to results from the GUI study, which is a national longitudinal study of children in the Republic of Ireland. The CCLaS study aims to highlight the modifiable social, economic, and cultural dimensions of childhood obesity. It is anticipated that this will highlight areas of action for policymakers, planners, and developers with a responsibility for addressing childhood obesity and creating sustainable healthy environments.

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Authors' Contributions

EK wrote the original manuscript. This was modified and adapted by all other authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Principal questionnaire from the Cork Children's Lifestyle Study (CCLaS).

[[PDF File \(Adobe PDF File\), 282KB - resprot_v3i3e44_app1.pdf](#)]

Multimedia Appendix 2

Child questionnaire from the Cork Children's Lifestyle Study (CCLaS).

[[PDF File \(Adobe PDF File\), 477KB - resprot_v3i3e44_app2.pdf](#)]

Multimedia Appendix 3

Parent questionnaire from the Cork Children's Lifestyle Study (CCLaS).

[[PDF File \(Adobe PDF File\), 945KB - resprot_v3i3e44_app3.pdf](#)]

Multimedia Appendix 4

Food diary template from the Cork Children's Lifestyle Study (CCLaS).

[[PDF File \(Adobe PDF File\), 1MB - resprot_v3i3e44_app4.pdf](#)]

Multimedia Appendix 5

Individual, family and environmental factors measured by the CCLaS questionnaires.

[[PDF File \(Adobe PDF File\), 183KB - resprot_v3i3e44_app5.pdf](#)]

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Abbreviations

- BP:** blood pressure
- CCLaS:** Cork Children's Lifestyle Study
- GUI:** Growing Up in Ireland study
- LSAC:** The Longitudinal Study of Australian Children
- PPS:** probability proportionate to size
- SOP:** standard operating procedures

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Protocol

Heavy Lifting at Work and Risk of Ischemic Heart Disease: Protocol for a Register-Based Prospective Cohort Study

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Abstract

Background: There are theoretical grounds to suspect that heavy lifting at work is an important risk factor for ischemic heart disease (IHD). However the relationship has not been sufficiently acknowledged by empirical studies. Positive and statistically significant associations have been found in studies that utilize self-reported exposure data. Such studies are, however, prone to reporting bias. All else equal, people with a poor cardiovascular fitness/health may have a higher propensity to perceive their work environment as heavy.

Objective: The study described in the present protocol aims to investigate the relationship between heavy lifting at work and IHD by use of material and methods that are free from reporting bias.

Methods: This is a register-based prospective cohort study. Male blue-collar workers in Denmark will be identified and followed through national registers, from 2001-2010, for hospital treatment or death due to IHD. Relative rates of IHD between “workers in occupations likely to involve heavy lifting” and “other blue-collar workers” will be estimated through Poisson regression.

Results: Results are expected to be ready in mid-2015.

Conclusions: Since this is not a randomized study, it cannot confirm etiological hypotheses. It may, however, confirm that employment in occupations that involve heavy lifting is a predictor for IHD and thereby lend support to the hypothesis of a causal relationship.

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KEYWORDS

occupational health; cardiovascular disease; manual work; cohort study

Introduction

Background

A positive association between occupational physical demands, cardiovascular disease, and mortality has been found in several cohorts [1-8]. However, the specific types of occupational physical demands conferring the increased risk for cardiovascular disease remain unsettled [8].

A retrospective case-control study has indicated that occupational heavy lifting increases the risk for acute myocardial infarction while occupational walking and leisure time physical activity decrease the risk [3]. Moreover, in a recent prospective

multi-adjusted study [9], men reporting heavy lifting at work had 55% increased risk for ischemic heart disease (IHD). Occupational heavy lifting has also been shown to impose an acute cardiovascular strain, excessively raising blood pressure for a prolonged period of time [2].

However, the two previous studies on the relationship between occupational heavy lifting and IHD may be biased by the self-reported measure of occupational heavy lifting. For example, it has been shown that people with myocardial infarction tend to remember and report previous physical activity levels differently than comparable control persons [10]. The largest recall bias was found for estimated associations between

myocardial infarction and perception of occupational workload and repetitive or heavy lifting at work.

Therefore, studies investigating the risk for IHD among blue collar occupational groups likely to be involved in occupational heavy lifting compared with blue collar occupational groups not likely to be involved in occupational heavy lifting are needed.

Objectives

The present study aims to investigate the relationship between heavy work and risk of IHD, among men in the general working population of Denmark.

The following hypotheses will be tested: (1) the rate of hospital treatment or death due to IHD is higher among blue-collar workers in occupations likely to involve heavy lifting than it is among blue-collar workers in occupations less likely to involve heavy lifting, and (2) the rate of death due to IHD is higher among blue-collar workers in occupations likely to involve heavy lifting than it is among blue-collar workers in occupations less likely to involve heavy lifting.

The above hypotheses are operationalizations designed to shed light on the following underlying hypotheses: (1) prolonged periods of occupational heavy lifting are likely to increase the risk of IHD, and (2) prolonged periods of occupational heavy lifting are likely to increase the risk of death due to IHD, either through an increased risk of occurrence or an increased risk of death given occurrence of the disease.

The hypotheses are based on the following theoretical arguments: heavy lifting is well known to acutely increase blood pressure. Several hours work per day of lifting-induced elevated blood pressure with minor possibilities for sufficient restitution may cause endothelial micro ruptures and damage of the arteries [1], inducing absorption of lipids and other pathogenic substances in the arterial wall leading to arteriosclerosis [11]. These conditions are associated with an increased risk of IHD [12].

Methods

Data Source

The study will use a database obtained through a record-linkage between four national registers—the central person register [13], the hospital patient register [14], the cause of death register [15], and the employment classification module. The central person register contains information on gender, addresses, and dates of birth, death, and migrations for every person who is or has been an inhabitant of Denmark sometime between 1968 and present time. A person's occupation and industry are, since 1975, registered annually in the employment classification

module. Since 1994, the occupations are coded according to the Denmark International Standard Classification of Occupations (DISCO-88) [16], which is a national version of the International Standard Classification of Occupations (ISCO-88). The national hospital register has existed since 1977 and contains data from all public hospitals in Denmark (more than 99% of all admissions). From 1977 to 1994, the register only included inpatients but from 1995 it also covers outpatients and emergency ward visits. Since 1994, the diagnoses are coded according to the International Classification of Diseases, 10th revision (ICD-10) [17].

The study will comply with The Act on Processing of Personal Data (Act No. 429 of 31 May 2000), which implements the European Union Directive 95/46/EC on the protection of individuals. The data usage is approved by the Danish Data Protection Agency, journal number: 2001-54-0180. According to Danish law, questionnaire and register-based studies do not need approval by ethical and scientific committees, nor informed consent.

Occupational Categories

The occupational categories to be used in the hypothesis tests are given, in terms of DISCO-88 codes, in Table 1. The occupations considered to be strongly associated with heavy lifting were selected in accordance with expert opinion by Professor Holtermann, National Research Centre for the Working Environment (NRCWE). The opinion of Holtermann was seconded by Professor Karen Sjøgaard, University of Southern Denmark. The selection was done in connection with the design of an earlier study, which would investigate the association between heavy lifting and retinal detachment. Data from the Danish work environment cohort survey (DWECS) in the year 2000 [18] were used to confirm that the occurrence of heavy lifting among male workers who belong to Holtermann's group is significantly higher than it is among workers who belong to the other occupational category. Responses to the following questions were considered: (1) How much of your time at work do you carry or lift objects? (Almost all the time; Approximately 3/4 of the time; Approximately 1/2 of the time; Approximately 1/4 of the time; Rarely/very little; Never), and (2) How much does what you carry or lift typically weigh? (Less than 3 kg; 3-10 kg; 11-29 kg; 30-49 kg; 50 kg or more).

The proportion who reported that they carry or lift objects approximately one-quarter of the time or more was statistically significantly higher among males in Holtermann's group than it was among other blue-collar workers. The same holds for the ones who reported that they carry or lift objects approximately one-quarter of the time or more and that the objects typically weigh 30 kg or more.

Table 1. Occupational categories according to DISCO-88.

Occupational category	DISCO-88
Holtermann's group (occupations that are strongly associated with heavy lifting)	
	712. Building frame and related trades workers
	921. Agricultural, forestry and fishery laborers
	931. Construction laborers
	933. Transport and storage laborers
Other blue-collar workers (occupations in which heavy lifting is less likely to occur)	
	All workers with a first digit DISCO-code equal to 6 (agricultural trades workers), 7 (craft and related trades workers), 8 (plant and machine operators and assemblers), or 9 (elementary occupations). Except those that belong to Holtermann's group.

Statistics on Lifting, Smoking, and BMI

We know that a high body mass index (BMI) and smoking are important risk factors for IHD. Unfortunately, the data material of the present study does not contain individual-based information on these factors. We have, however, individual-based data on a random sample (ca. 1 per 400) of our study population (DWECS 2000), which we can use to evaluate the possible influence of the two risk factors. In [Table 2](#), we give estimated percentages of occupational lifting, by occupational group. We also give statistics on BMI and smoking habits.

As seen in [Table 2](#), the proportion of overweight workers was significantly lower among workers in Holtermann's group than it was among other blue-collar workers. To get an idea of the extent that this factor may influence the rate ratio of IHD between the two groups, we calculated the expected rate ratio under the assumption that the groups are equal in all respects other than the BMI distribution. According to our calculations, the expected rate ratio, $E[RR]$, for IHD (Holtermann's group

vs other blue-collar workers) equals 0.96 (95% CI 0.91-1.01) under the assumption that the groups are equal in all respects other than the BMI distribution. The standard error of the logarithm of the estimate equals 0.0274. The standard error and the confidence interval are based on Gauss propagation of error formulas. The point estimate is based on the following equation:

$$E[RR] = (1 + p_1(RR_1 - 1) + p_2(RR_2 - 1)) / ((1 + q_1(RR_1 - 1) + q_2(RR_2 - 1)))$$

where RR_1 is the rate ratio for IHD among people in the category $25 \leq BMI < 30$ vs $BMI < 25$ and RR_2 is the rate ratio between the categories $BMI \geq 30$ and $BMI < 25$. The p_i 's are the proportions in the various BMI categories in Holtermann's group while the q_i 's are the proportions among other blue-collar workers. The proportions were estimated through DWECS 2000, while the rate ratio for IHD, by BMI group, was estimated on workers registered in DWECS 1990, 1995, 2000, and 2005 through a follow-up (1991-2009) in the national registers described in the Methods section. The estimated rate ratio for IHD, by BMI category is given in [Table 3](#).

Table 2. Percentage of male workers exposed to occupational lifting, smoking, and high body mass index (BMI) according to DWECS 2000, by occupational category.^a

Exposure category	Holtermann's group n (%)	Other blue-collar workers n (%)	OR	95% CI
Lifting $\geq 1/4$ of work hours	206 (79.2)	512 (47.7)	4.17	3.02-5.76
Lifting $\geq 1/4$ of work hours ("The objects weigh typically 30 kg or more.")	43 (16.5)	114 (10.6)	1.67	1.14-2.44
BMI ≥ 25	113 (43.7)	574 (53.8)	0.66	0.50-0.87
BMI ≥ 30	25 (9.7)	116 (10.9)	0.88	0.56-1.38
Current smoker	118 (45.4)	481 (45.0)	1.02	0.78-1.34

^aThe total number of observations varied (due to missing values) between 259 and 260 in Holtermann's group and between 1067 and 1073 among other blue-collar workers.

Table 3. Rate ratio (RR) with 95% confidence interval (CI) for hospital treatment or death due to IHD, 1991-2010, by body mass index (BMI) in a representative sample of Danish employees.^a

BMI	Persons	Person years	Cases	RR	95% CI
<25	7078	89,514	180	1.00	-
25 ≤ BMI < 30	4059	41,564	186	1.41	1.14-1.74
≥30	1244	10,454	87	2.69	2.08-3.49

^aThe analysis was controlled for gender, age, and calendar time.

Statistics on Other Occupational Exposures

In the last section, we looked at BMI and smoking. In this section, we will look at statistics on certain work environmental factors, which theoretically may influence the rate of IHD. The following occupational exposures have been associated with an increased risk for subsequent IHD: noise [19], poor decision latitude [20], high job insecurity [21], shift work [22], prolonged working hours [23], and air pollution [24].

These factors are not as influential as BMI—being obese versus normal weight increases the risk with almost 200%, while the various work environmental exposures typically are associated with an elevated risk of between 5 and 25% [19]. Nevertheless, if we find that the rate of IHD is significantly higher in “occupations that are strongly associated with heavy lifting” than in “occupations in which lifting is less likely to occur”, then we want to rule out the possibility that the result is due to an increased exposure to other work environmental risk factors.

DWECS 2000 does not provide any reliable measure of exposure to air pollution. It contains, however, questions that can be used to obtain measures of the other above mentioned risk factors. In Table 4, we give estimated percentages of exposure to noise,

poor decision latitude, high job insecurity, shift work, and prolonged working hours, by occupational category.

A person was categorized as exposed to:

- loud noise, if he replied “Approximately 1/4 of the work hours” or more to the question “Are you subjected to noise that is so loud that you have to raise your voice in order to talk to others?” He was categorized as unexposed if he replied “Rarely/very little” or “Never”
- poor decision latitude, if he replied “Rarely” or “Never/Almost never” to the question “Do you have a significant influence in the decision making at your work?”
- high job insecurity, if he answered “Yes” to any of the following questions: “Are you worried about becoming unemployed?” or “Are you worried about difficulties in finding a new job with your present qualifications?”
- prolonged working hours, if he worked 41 hours or more per week
- shift or night work, if the normal placement of his work was either fixed at night or shifting (working on two shifts, three shifts, or irregularly during the day/week according to special schedule or rotation). He was categorized as unexposed if he replied “Fixed day duty”, “Fixed morning duty”, or “Fixed evening shift/evening work”.

Table 4. Percentage of male workers exposed to loud noise, low decision latitude, high job insecurity, prolonged working hours, and shift or night work, according to DWECS 2000, by occupational category.^a

Exposure category	Holtermann’s group n (%)	Other blue-collar workers n (%)	OR	95% CI
Loud noise ≥¼ of work hours	116 (44.6)	463 (43.2)	1.06	0.81-1.39
Poor decision latitude	76 (29.2)	331 (30.0)	0.92	0.68-1.24
High job insecurity	62 (26.4)	311 (32.2)	0.76	0.55-1.04
Prolonged working hours	46 (17.7)	318 (29.9)	0.50	0.36-0.71
Shift or night work	22 (8.5)	216 (20.2)	0.37	0.23-0.58

^aThe total number of observations varied (due to missing values) between 235 and 260 in Holtermann’s group and between 967 and 1072 among other blue-collar workers.

Study Design

The study population consists of all male inhabitants of Denmark, who at baseline (January 1, 2001) were 21-59 years old and belonged to any of the two occupational groups given above. These people will be followed in our national registers, from January 1, 2001 to December 31, 2010. Approximately half a million working men will be included in the study.

The following clinical endpoints will be considered: (1) hospital treatment or death with IHD as principal diagnosis/cause of

death (the case definition includes these ICD-10 codes: I20 angina pectoris, I21 acute myocardial infarction, I22 subsequent myocardial infarction, I23 certain current complications following acute myocardial infarction, I24 other acute ischemic heart diseases, I25 chronic ischemic heart disease), and (2) death with IHD as principal cause of death.

The study population will be followed, first for death or hospital treatment due to IHD and then for death due to IHD. Only those who were free from IHD-related hospital visits throughout the calendar year preceding baseline will be included in the analysis.

For each of the two endpoints, each of the included individuals will be followed until any of the following events occur: he reaches the clinical endpoint of the follow-up, he emigrates, he dies, or the study period ends. Person years at risk (PYRS) will be calculated for each individual.

We will use Poisson regression to estimate rate ratios between Holtermann's blue-collar workers and all other blue-collar workers, while adjusting for age (10-year age groups). The rate ratios will be presented with 95% confidence intervals. PROC GENMOD in SAS version 9.3 will be used to implement the analysis.

Hypothesis Testing Criteria

A hypothesis is confirmed (regarded as statistically significant) if the lower boundary of the 95% confidence interval of its associated rate ratio exceeds one. The significance level is thereby set at .025.

If the first hypothesis is confirmed and the rate ratio of the second hypothesis exceeds one, then we will conclude that the first of the underlying hypotheses is supported by the data. If the second hypothesis is confirmed, then we will conclude that

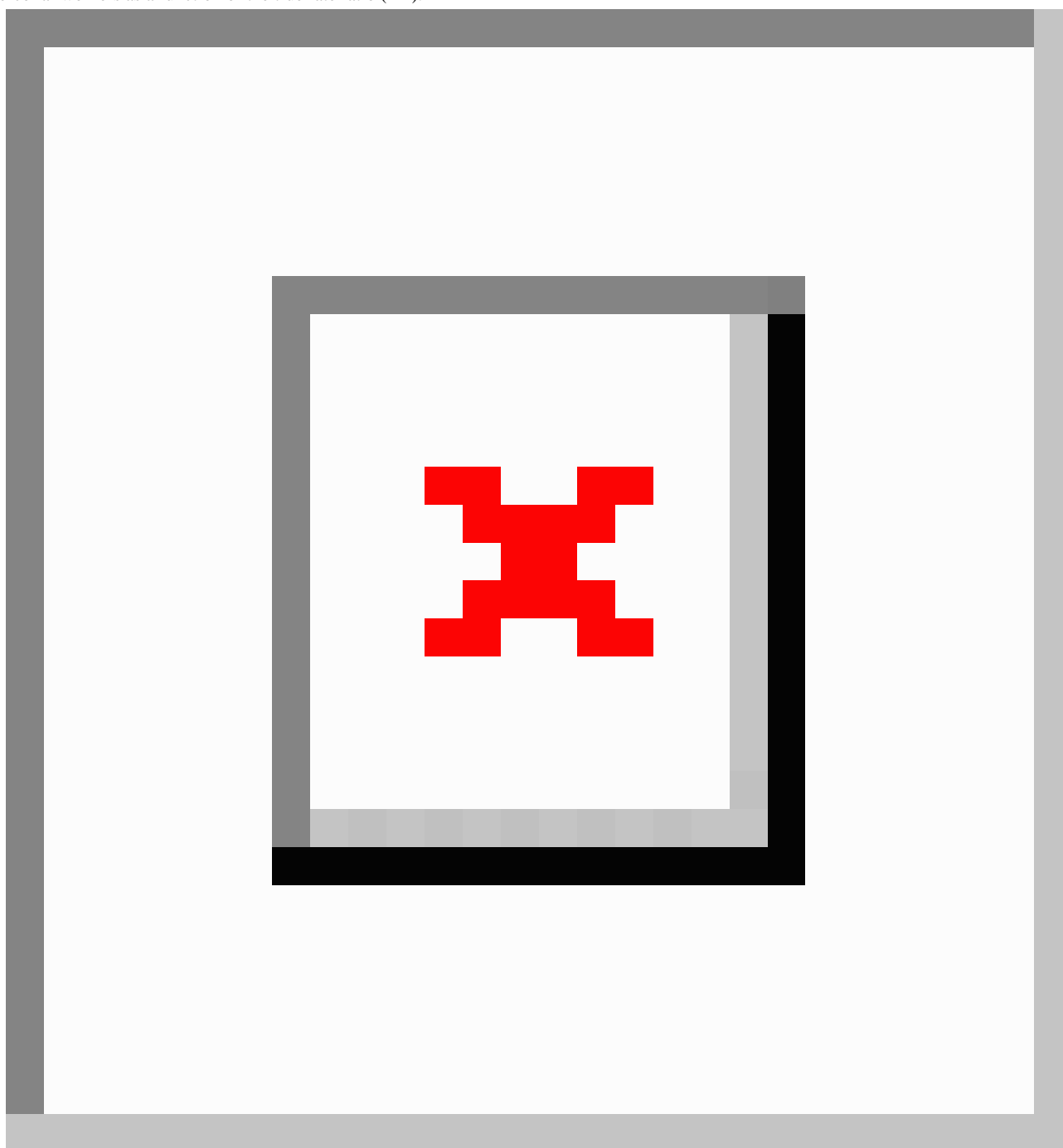
the second of the underlying hypotheses is supported by the data.

Power Calculations

A 10-year follow-up (2001-2010), including all economically active men in Denmark aged 21-59 years in January 2001, yields ca. 420 cases of hospital treatment or death due to IHD per 100,000 person years, and 23 cases of death due to IHD per 100,000 person years. At baseline, 8.73% (112,699/1,291,665) of the workforce belonged to Holtermann's group while 31.38% (405,385/1,291,665) belonged to the group "other blue-collar workers". If we assume that the number of cases is proportional to the number of people in the various job groups, then the expected numbers of cases of hospital treatment or death due to IHD are approximately 4650 in Holtermann's group and 16,000 among the other blue-collar workers. The corresponding numbers for death due to IHD are 255 and 880.

With the above data as input, the statistical powers of the tests are given as a function of the true rate ratio in [Figure 1](#). The calculations are based on the Poisson distribution, the propagation of error formulas, and the central limit theorem.

Figure 1. Approximate power curves for the hypothesis that the rate of IHD is higher among men in Holtermann's group than it is among other blue-collar workers as a function of the true rate ratio (RR).



Sensitivity Analysis 1

Since the latency period for ischemic heart disease is long [25], a person will be kept in his baseline exposure category throughout the follow-up regardless of whether or not he shifts to another job or retires from the labor market during the follow-up.

During the study period, the participants were eligible for an old age pension at the age of 65. It was, however, also possible to retire prematurely at the age of 60, according to an optional public insurance policy. It is possible that heavy lifting at work influences the propensity to opt for early retirement. It is also possible that early retirement influences the risk of IHD. Early

retirement might, in other words, be a moderating factor for the risk of subsequent IHD as a function of heavy lifting at work, among people who are 60 years or older. If this is the case, then we might not be able to generalize the results of the present study to nations or time periods with other retirement schemes.

To shed some light on this issue, we will perform a sensitivity analysis where we censor the follow-up whenever a participant reaches age 60. The clinical endpoint of the sensitivity analysis will be hospital treatment or death due to IHD as principal diagnosis/cause of death.

Sensitivity Analysis 2

The inclusion/exclusion criteria of the primary analysis are based solely on information from the calendar year preceding baseline. It would have been possible to involve information from more than one calendar year; however, since we want our estimates to be representative of the situation among all of the concerned workers who were healthy enough to be classified as economically active at baseline, we elected our exclusion criteria parsimoniously. In the primary analysis, we exclude all workers who were treated for IHD sometime during the calendar year preceding baseline and, by doing so, we have ascertained that an observed instance of hospital treatment during the follow-up is a new episode rather than a revisit in a course of treatment that had already started before baseline. We cannot know, however, if this was the first occurrence of the disease ever.

It is possible that some workers, due to ischemic heart disease, changed from an occupation that entails heavy lifting to an occupation that does not entail heavy lifting, a few years prior to baseline. If this is the case, then, from an etiological viewpoint, our estimates will be biased. We will address this issue with a sensitivity analysis that only includes those who lived in Denmark, were free from IHD-related hospital contacts, and belonged to the same occupational category throughout a 3-year period prior to baseline. The clinical endpoint will be hospital treatment or death due to IHD. Since our project does not have access to information about people who are younger than 20 years and the inclusion/exclusion criteria are based on a 3-year period, we can only include people who were at least 23 years old at baseline. In all other respects, we will use the design of the primary analysis.

Discussion

Study Protocol

With this study protocol, we define the hypotheses, inclusion criteria, statistical models, and test criteria completely before we look at any relationship between the exposure and outcome variables in our data. By doing so, we have eliminated hindsight bias. The prospective design and the exclusion of prevalent cases ascertain that the exposure takes place before the outcome. The size of the study gives us a tremendous statistical precision and, since we are dealing with registers that cover the entire

population of Denmark, we do not have any problems with sampling bias, response bias, or volunteer bias.

Challenges

The drawback of the study is that it lacks individual-based data on some quite important predictors for IHD, such as smoking [26], BMI [27], physical fitness [28], blood pressure, and cholesterol [29]. It is well documented that the distribution of risk factors for IHD differs between social groups [30,31] and that the rates of IHD generally are lower among white-collar workers compared with blue-collar workers. To mitigate the possible influence from uncontrolled risk factors, we decided to only include blue-collar workers in our comparison group. The drawback of this decision is that the comparison group also, to some degree, will contain elements of heavy lifting.

We used data from a survey on a random sample of the study population to look at differences, between the group associated with heavy lifting and other blue-collar workers, in the prevalence of smoking, overweight, obesity, exposure to noise, poor decision latitude, high job insecurity, prolonged working hours, and shift work. We did not find any difference in smoking prevalence but we found that the prevalences of overweight, prolonged working hours, and shift work were statistically significantly lower among people in the group associated with heavy lifting than they were in the comparison group. These differences are likely to bias our estimate slightly in the opposite direction of the hypothesis, which decreases the probability of a false positive finding.

Another aspect of the study that needs to be considered is the possibility of detection or referral bias. The perceived adverse effects of a heart condition might increase with heavy lifting activities. Hence, the probability of becoming aware of and the propensity to seek medical treatment for a minor IHD might be higher among people who are exposed to heavy lifting at work than it is among other blue-collar workers. This potential source of bias points in the same direction as our hypothesis and would thereby increase the probability of a false positive finding. The probability that referral bias causes us to erroneously conclude that the data support the first of our underlying hypotheses is, however, decreased by our testing criteria, which tell us that we only are allowed to draw such a conclusion if also the rate ratio of death due to IHD is greater than one.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

DISCO-88: Denmark International Standard Classification of Occupations

DWECS: Danish work environment cohort survey

ICD-10: International Classification of Diseases, 10th revision

IHD: ischemic heart disease

NRCWE: National Research Centre for the Working Environment

RR: rate ratio

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Protocol

Long Working Hours and Subsequent Use of Psychotropic Medicine: A Study Protocol

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Abstract

Background: Mental ill health is the most frequent cause of long-term sickness absence and disability retirement in Denmark. Some instances of mental ill health might be due to long working hours. A recent large cross-sectional study of a general working population in Norway found that not only “very much overtime”, but also “moderate overtime” (41-48 work hours/week) was significantly associated with increased levels of both anxiety and depression. These findings have not been sufficiently confirmed in longitudinal studies.

Objective: The objective of the study is to give a detailed plan for a research project aimed at investigating the possibility of a prospective association between weekly working hours and use of psychotropic medicine in the general working population of Denmark.

Methods: People from the general working population of Denmark have been surveyed, at various occasions in the time period 1995-2010, and interviewed about their work environment. The present study will link interview data from these surveys to national registers covering all inhabitants of Denmark. The participants will be followed for the first occurrence of redeemed prescriptions for psychotropic medicine. Poisson regression will be used to analyze incidence rates as a function of weekly working hours (32-40; 41-48; > 48 hours/week). The analyses will be controlled for gender, age, sample, shift work, and socioeconomic status. According to our feasibility studies, the statistical power is sufficient and the exposure is stable enough to make the study worth the while.

Results: The publication of the present study protocol ends the design phase of the project. In the next phase, the questionnaire data will be forwarded to Statistics Denmark where they will be linked to data on deaths, migrations, socioeconomic status, and redeemed prescriptions for psychotropic medication. We expect the analysis to be completed by the end of 2014 and the results to be published mid 2015.

Conclusions: The proposed project will be free from hindsight bias, since all hypotheses and statistical models are completely defined, peer-reviewed, and published before we link the exposure data to the outcome data. The results of the project will indicate to what extent and in what direction the national burden of mental ill health in Denmark has been influenced by long working hours.

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KEYWORDS

occupational health; working time arrangements; mental health; prescription drugs; psychotropic medicine

Introduction

Mental Health and Long Working Hours

Mental health problems have become the biggest single cause for a disability benefit claim in the Organization for Economic Cooperation and Development countries. In Denmark, they account for almost 50% of all new claims [1]. The research literature suggests that some instances of mental ill health might be due to long working hours. It has been shown that long working hours are associated with short sleep [2-4] and fatigue [2,4-6], and that both of these conditions are predictors of psychiatric disorders [7-13]. There are, however, also some prophylactic effects of long working hours. All else being equal, long working hours would increase income, and thereby, decrease the risk of financial strain, which is a condition proven to be highly predictable of psychiatric disorders [14-16]. Some individuals who work long hours appear to be in a situation where there is an imbalance between the prophylactic and the pathogenic effects of the prolonged work [17]. From this viewpoint, some cases of mental ill health would be caused by long working hours, while others would be prevented in that prolonged work might solve problems which otherwise would lead to mental ill health.

The Danish Government and Increased Working Hours

The Danish government wants to increase the total number of work hours in the nation by: (1) decreasing the number of hours that are lost due to sickness absence and early retirement, and (2) encouraging the ones that are working, to work longer hours [18]. From this perspective, we want to know if there is a positive, negative, or no correlation between long working hours and incidence of psychiatric disorders in the Danish working population, in other words, if pathogenic effects of long working hours outweighs the salutogenic effects or vice versa. We are especially interested in the situation among the people who perform moderate overtime work (41-48 work hours/week), that is, overtime work which lies within the limits of the European working time directive. If there is a nonnegligible correlation between long working hours and subsequent mental ill health, then this needs to be taken into account in the planning and evaluation of strategies aimed at getting more people to work extra hours.

The existing literature does not provide the information we need to settle this question.

Studies and Findings

A recent large cross-sectional study of a general working population in Norway found that not only “very much overtime” (49-100 work hours/week), but also “moderate overtime” (41-48 work hours/week) was significantly associated with increased levels of both anxiety and depression [19]. These findings have, however, not been sufficiently confirmed in studies that utilize longitudinal designs. The hypothesis that “very much overtime” is a predictor of mental disorders is supported by three prospective company based studies [20-22]. Suwazono et al [20] focused on the development of mental disorders among workers in a large telecommunication enterprise in Japan. They

found that the odds for having developed mental disorders at the end of a four year follow-up period were higher among those who worked > 12 hours/day at baseline than they were among those who worked ≤ 8 hours/day. The estimated odds ratio was statistically significant among the men, but not among the women. Virtanen et al [22] focused on the development of depression and anxiety symptoms in a group of middle-aged British civil servants. They found that those who worked more than 55 hours/week at baseline, compared with those who worked 35-40 hours/week, had a higher propensity for developing depression and anxiety symptoms during an approximately five year follow-up period. Based on the same database, it has also been shown that the civil servants who worked more than 55 hours/week had a higher propensity for developing sleeping disorders [21]. The latter result is, however, contradicted by a large population-based prospective study wherein the odds for having developed sleeping disorders at the end of a five year follow-up period were lower among those who often worked more than 48 hours/week at baseline than they were among other employees [23].

The company-based studies mentioned above also compared the effect of “moderate overtime” (defined as 8-12 work hours/day by Suwazono et al, and 41-55 work hours/week by Virtanen et al) [20-22] with the effect of “normal working hours” (defined as ≤ 8 work hours/day by Suwazono et al, and 35-40 work hours/week by Virtanen et al) [20-22]. The studies suggest a tendency for higher risks among those with moderate overtime work, but the contrast is not statistically significant in any of the studies.

Aim and Hypothesis

The null-hypothesis of the present project is that long working hours, to the extent that it is currently practiced in Denmark, neither adds to nor subtracts from the national burden of mental ill health.

The project aims at testing the above hypothesis in a prospective cohort study on a random sample of the Danish working population. The null-hypothesis will be rejected if subsequent rates of mental ill health (manifested by the use of psychotropic medicine) among people with long working hours at baseline differ significantly from those among people with normal working hours. The analysis will be adjusted for gender, age, socioeconomic status, and shift work. It will only include those who are free from symptoms at baseline.

Methods

Ethics Approval

The study will comply with The Act on Processing of Personal Data (Act No. 429 of May 31, 2000), which implements the European Union Directive 95/46/EC on the protection of individuals.

Data Material

The data material of the project will be obtained through a linkage of data from the Copenhagen Psychosocial Questionnaire (COPSOQ) study sample of 2004, the Danish National Working Environment Survey (DANES) of 2008, and

the Danish Work Environment Cohort Study (DWECS) of 1995, 2000, 2005, and 2010 with data from the Central Person Register (CPR), the Employment Classification Module (ECM), and the Danish National Prescription Registry (DNPR). The participants' unique personal identification numbers will be used as the key in the linkage procedure. DNPR covers all purchases of prescription drugs at pharmacies in Denmark since 1995 [24]. The CPR has existed since 1968, and contains dates of deaths and migrations in the Danish population [25]. A person's occupation, industry, and socioeconomic status are, as of 1975, registered annually in the ECM [26]. Socioeconomic status is coded in accordance with Statistics Denmark's official socioeconomic classification [27]. The socioeconomic status (SES) code among employees is based on the first digit of the Danish version of the International Standard Classification of Occupations (ISCO-88) [28], and contains the following categories: (1) legislators, senior officials, and managers (ISCO-88 group 1), (2) professionals (ISCO-88 group 2), (3) technicians and associate professionals (ISCO-88 group 3), (4) workers in occupations that require skills at a basic level (ISCO-88 group 4-8), (5) workers in elementary occupations (ISCO-88 group 9), and (6) gainfully occupied people with an unknown occupation (missing ISCO-88 code).

The COPSOQ study sample is a random sample, which comprises 4732 people, 20-59 years of age, whereof 3517 are wage earners [29]. DANES is based on a random sample of the Danish population in 2008. It contains responses from 6531 people 18-59 years of age, of which 4919 are employees. The DWECS is an open cohort study, which was initiated in 1990 with a random sample of people 18-59 year of age in the Danish population. The cohort has thereafter been supplemented with young people and immigrants so as to obtain a representative cross-sectional study of at least 5000 employees every fifth year [30].

The reported response rates were 80, 75, 60, 62, 66, and 48 percent for DWECS 1995 [31]; DWECS 2000 [31]; COPSOQ 2004 [29]; DWECS 2005 [32]; DANES 2008 [33]; and DWECS 2010 [34], respectively. These response rates are, however, only correct for the data that were collected prior to 2000. In May 2000, a new law was passed which made it easier for citizens to be registered as permanent nonrespondents in research surveys based on random samples from the central person register; a registration which protects them from being contacted by researchers. The reported response rates above do not take the registered nonrespondents into account. For example, 14% of all employees in Denmark were registered as permanent nonrespondents in 2008 [35]. If we take people from this group into account then the response rate for the DANES survey in 2008 will fall from the reported 65.88% (6531/9913) to 56.66% (6531/11,527).

The COPSOQ, the DANES, and the DWECS surveys contain person-based information on weekly working hours, calculated by adding the hours worked in secondary jobs to the ones in a primary job. The wording of the questions differs, however, slightly between the various questionnaires. The DWECS questionnaires of 1995, 2000, and 2005 ask for weekly working hours in current jobs or (if the person is momentarily out of work) in the last held job. DWECS 2010 asks for current weekly

working hours without further specification. COPSOQ and DANES ask for average working hours during the one year period preceding the time of the interview. The COPSOQ questionnaire only allowed participants to report between 0 and 99 working hours per week, while the other questionnaires allowed an unlimited number of hours. Another peculiarity of the COPSOQ questionnaire is that it uses a single question to ask for the combined number of hours worked in primary and secondary jobs, while the other questionnaires use one question for the number of hours worked in the primary job and another one for the hours worked in secondary jobs. The surveys also contain information on the participants' normal work schedules. Again, the questions and response categories vary slightly between the questionnaires, but all of them can identify workers who are either on fixed night shifts or rotational shift work schedules. The exact wordings (in Danish) of the used questions are given in the appendix (see [Multimedia Appendix 1](#)). A translation into English is given; see [Multimedia Appendix 2](#).

Primary Analysis

Case Definition

The medical products in the DNPR are coded in accordance with the Anatomical Therapeutic Chemical (ATC) system. In the present project, a person will become a case if and when he or she redeems a prescription for drugs in the ATC-code category N05 (psycholeptica) or N06 (psychoanaleptica). The psycholeptic category contains antipsychotics, anxiolytics, hypnotics, and sedatives, while the psychoanaleptic category contains antidepressants, psychostimulants, and antidementia drugs.

Follow-Up and Inclusion Criteria

Each of the included samples will be followed for a period of two to five years, beginning at the start of the calendar year succeeding the one in which they were sampled. People should be between 21 and 59 years old at the start of the follow-up period and, according to the questionnaire, employed with 32 or more weekly work hours around the time of the interview, to be eligible for inclusion. The sample from DWECS 2010 will be followed for two years. The sample from the DANES 2008 will be followed for four years. The remaining samples will be followed for five years. A participant will be censored if and when he or she dies or emigrates. Person years at risk will be calculated for each participant. People who redeemed a prescription for a medication with an ATC-code that belongs to the case definition, during the calendar year preceding baseline, will not be included. A participant who reaches the clinical endpoint of the study will not be allowed to reenter the follow-up. In other words, there will be maximum one case per person.

Statistical Model

We will use Poisson regression to analyze incidence rates of redeemed prescriptions for psychotropic medicine as a function of weekly working hours (32-40; 41-48; > 48 hours/week). The analysis will be controlled for gender, age (10 year classes), sample (DWECS 1995; DWECS 2000; COPSOQ 2004; DWECS 2005; DANES 2008; and DWECS 2010), shift work (fixed night shifts or rotational shift work schedules vs other),

and SES (legislators, senior officials and managers; professionals; technicians and associate professionals; workers in occupations that require skills at a basic level; workers in elementary occupations; and gainfully occupied people with an unknown occupation). With SES we mean socioeconomic status, according to the employment classification module, during the calendar year of the baseline interview. The logarithm of person years at risk will be used as offset. A likelihood ratio test will be used to test the null-hypothesis, which states that the analyzed rates are independent of weekly working hours. The significance level is set to 0.05.

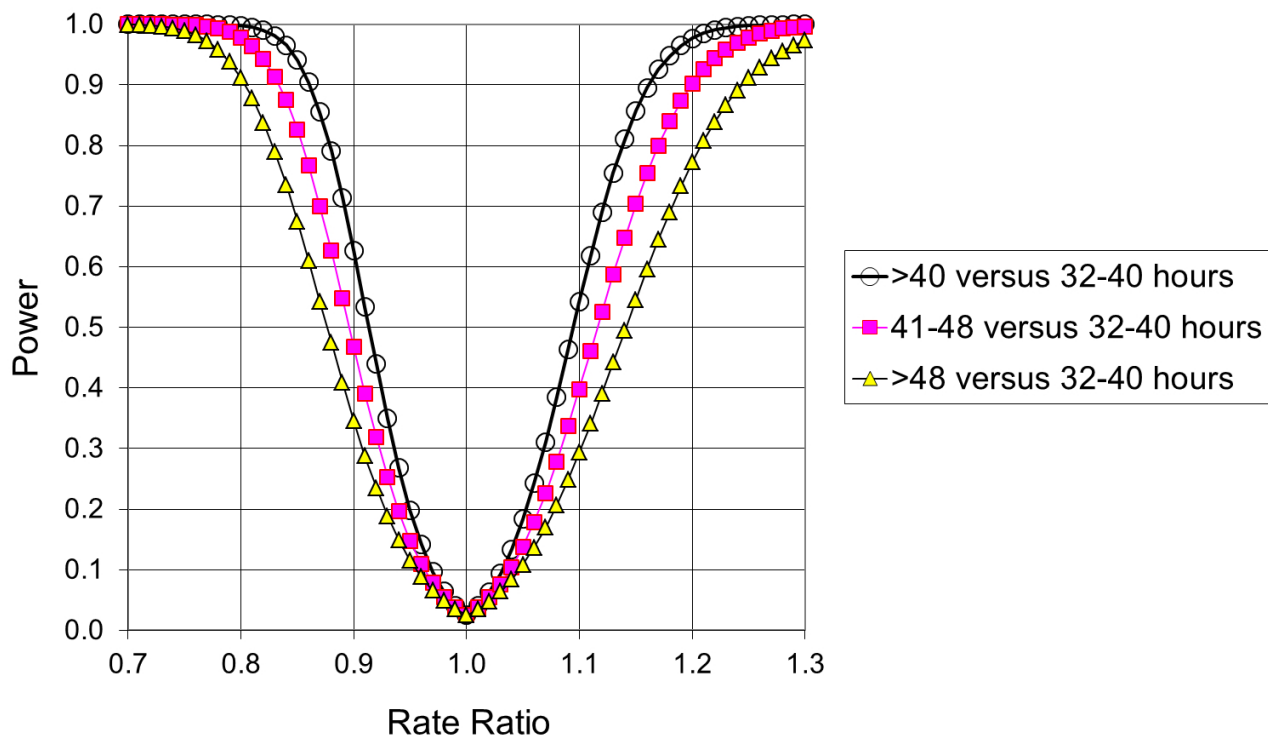
Power Calculations

Based on rates calculated through DNPR in the time period 2001-2005, we expect on average approximately 25 new cases per 1000 person years at risk (PYRS). We expect that the four follow-up periods of nonprevalent cases in the DWECS samples will provide approximately 68,000 PYRS, the five year

follow-up of the COPSOQ sample will provide 12,000 PYRS, and the four year follow-up of the DANES sample will provide 16,000 PYRS. Among the ones who worked 32 or more hours per week in 2000 according to DWECS, 26.7% worked more than 40 hours/week and 10.5% worked more than 48 hours/week.

With the above data as input, [Figure 1](#) illustrates the statistical powers to detect contrasts between normal working hours (32-40 hours/week) on one hand and “overtime work” (>40 work hours/week), “moderate overtime work” (41-48 work hours/week), and “very much overtime” (49-100 work hours/week) on the other, as a function of the true rate ratio. If, for example, the true rate ratio between moderate overtime workers and those with normal working hours is 1.2 then we have a 90% chance of detecting the difference; if it is 1.3 then the chance of detection is 99.7%. The power calculations are based on the Poisson distribution, the propagation of error formulas, and the central limit theorem.

Figure 1. Power of detecting differences in psychiatric morbidity rates in Denmark, between overtime workers and people with normal work hours, as a function of the true rate ratio.



Transitions Between Work Categories

The subjects of our study will be categorized according to their exposure status at baseline. They will thereafter be followed for five years. We do not have information about their work schedules during the follow-up, but wanted to ascertain that the exposure statuses were stable enough to make the study worth the while. To check this, we used DWECS data to cross-tabulate a worker's exposure status in 2000 with that in 2005. We included all who were economically active and 30 years or older in both waves. The exposure statuses were fairly stable over time; 68.3% (529/774) of the workers with long working hours and 83.28% (1240/1489) of the workers with normal working

hours in 2005 had the same working conditions five years earlier, while 67.9% (529/778) of the workers with long working hours and 83.50% (1240/1485) of the workers with normal working hours in 2000 had the same working conditions five years later. Cohen's kappa for agreement between the working hour category in 2000 and in 2005 was 0.52 (95% CI 0.48-0.55), which indicates a moderate agreement according to Landis and Koch [36].

Secondary Analyses

Regardless of whether or not the primary research hypothesis is confirmed, we will perform a series of secondary analyses. The interpretation of the results from these analyses will,

however, depend on the outcome of the primary hypothesis test. If the primary null-hypothesis is rejected, then the secondary analyses will be regarded as nested hypothesis tests. Otherwise, they will be regarded as hypothesis generating exploratory analyses, whose results need to be confirmed in an independent dataset before they can be deemed statistically significant.

With the endpoint and covariates of the primary hypothesis test, we will use likelihood ratio tests to check for possible two-way interaction effects between working hours and gender, age, shift work (fixed night shifts or rotational shift work schedules vs other), or socioeconomic status. Subsample analyses will thereafter be performed on data stratified, first by gender, then by age (21-39; 40-59 years old), then by shift work, and finally by socioeconomic status. In keeping with the principles of nested hypothesis testing, perceived differences in effect sizes between strata will not be considered statistically significant unless both the primary hypothesis test and the concerned two-way interaction effect are statistically significant.

In addition to the above, we will perform three separate analyses, in exactly the same way as we did in the primary analysis, but with endpoints defined by the following subsets of ATC-codes, N05B (anxiolytics), N05C (hypnotics and sedatives), and N06A (antidepressants).

Auxiliary Analysis Regarding Prescription Bias

Some people with sleeping disorders seek medical care to cope with the situation, while others do not. The same holds for anxiety and depressive disorders. We can therefore not know if an increased use of medicine is due to an increased need of treatment or an increased propensity to seek treatment. Our primary analysis will show if long working hours is associated with subsequent use of psychotropic medicine. Such a finding is of interest in itself. Obtained rate ratios can, however, only be interpreted as morbidity rate ratios if we can show that prescription bias is likely to be negligible.

Our data material allows us to evaluate whether or not prescription bias is present. The questionnaires that we describe in our project plan contain questions on mental health, which enable us to relate the prevalence of self-rated mental ill health to the prevalence of medicine users among people with long and normal working hours respectively.

In particular, the DANES questionnaire and the DWECs questionnaires of 1995, 2000, and 2005 contain all items needed to score the participants on the five item scale of the mental health inventory MHI-5, which is a subscale of the SF-36 general health index [37]. The MHI-5 scale is based on the following questions, all relating to the past four weeks: (1) "Have you been very nervous?"; (2) "Have you felt so down in the dumps that nothing could cheer you up?"; (3) "Have you felt calm and peaceful?"; (4) "Have you felt down-hearted and depressed?"; and (5) "Have you been happy?". Each question should be answered with one of the following response categories; "all of the time"; "most of the time"; "a good bit of the time"; "some of the time"; "a little of the time"; or "none of the time". The categories are scored, in the order listed, from 1 to 6 for the first, second, and fourth question, and from 6 to 1 for the third and fifth question. The score of the full scale is

a function of the scores of the items, and ranges between 0 and 100. The equation reads $y=100(x - n)/(5n)$, where y is the score of the full scale, n is the number of included items, and x is the sum of the scores of the included items. If the response is missing for two items or more then the whole scale will be categorized as missing. A lower score on the full scale indicates a poorer mental health, and a score which is less than or equal to 52 is regarded as an indicator of severe mental health problems [33,38,39]. The Danish translation of the SF-36 questionnaire has been validated [40] and the MHI-5 subscale has been shown to be reliable in the general population of Denmark (Cronbach alpha = 0.80) [41].

To shed some light on the matter of prescription bias, we will perform an auxiliary cross-sectional analysis, which compares odds ratios for poor self-rated mental health with odds ratios for use of psychotropic medicine among workers with long versus normal working hours. If either of these ratios is statistically significant, while the other one points in the opposite direction, then the idea that an increased/decreased rate of medicine usage can be interpreted as an increased/decreased rate of poor mental health is contradicted.

For this analysis, we will not include information from COPSOQ or DWECs 2010. Otherwise, the data sources are the same as the ones described for the primary analysis. Prevalent cases will not be excluded, but the rest of the inclusion/exclusion criteria will be the same as the ones of the primary analysis. The following case definitions will be employed for poor self-rated mental health and use of psychotropic medicine, respectively: (1) a score on the mental health inventory (MHI-5) that is less than or equal to 52, and (2) redemption of a prescription for a drug in the ATC-code category N05 (psycholeptica) or N06 (psychoanaleptica), during the calendar year of the interview.

Logistic regression will be used to model the odds of the outcomes as a function of weekly working hours (>40 hrs/week; 32-40 hrs/week). The analysis will be controlled for gender, age, socioeconomic status, shift work, and sample in the same way as was done in the primary analysis. Generalized estimating equations will be used to estimate the parameters. Observations from the same person will be treated as repeated measurements. A first order autoregressive correlation structure is assumed. The odds ratio (OR) between the exposed and the nonexposed will be calculated and presented with a 95% CI. The CI will be based on the empiric standard error. An OR will be considered statistically significant if the CI does not contain 1.

Approximately 16,500 employees will fulfill the inclusion criteria of this auxiliary analysis. The prevalence of poor self-rated mental health ($MHI-5 \leq 52$) among Danish employees was estimated to 7.3% in 2008 [33], while the corresponding prevalence for use of psychotropic medicine was 9.3% (according to a linkage between the ECM and the DNPR). With such a frequency of events, we estimate that the power to detect an OR of 1.2 or higher or 1/1.2 or lower between employees with long versus normal working hours will be at least 80% for either of the two outcomes.

Sensitivity Analyses

Exclusion of Workers With Poor Self-Rated Mental Health at Baseline

Workers who redeemed a prescription for psychiatric drugs in the year preceding baseline are excluded from the study. This is done to counteract the possibility of a healthy-worker bias. There is, however, a possibility of residual confounding, since mental health problems may exist also among workers who do not use prescription drugs. We want to know to what extent and in what direction the estimates to be obtained in the primary analysis would change if we were able to exclude all workers with mental health problems at baseline, regardless of whether or not they redeemed prescription drugs in the year preceding baseline. We will address this issue with a sensitivity analysis, which, in addition to excluding the participants who were prescribed medication, also excludes those with poor self-rated mental health at baseline, according to MHI-5 (score ≤ 52). Due to a discrepancy in the response categories of the MHI-5 questions, the sensitivity analysis cannot include data from COPSOQ 2004 and DWECS 2010. In all other respects, we will use the same statistical model as we did in the primary analysis. The parameters will be estimated first with medicine usage only, and then with medicine usage and/or poor self-rated mental health at baseline as exclusion criteria.

Are the Estimates Influenced By Job Satisfaction and Job Insecurity?

It has been shown that the psychosocial work environment is associated with mental health. According to a meta-analytic review by Stansfeld and Candy, common mental disorders were predicted by job strain, low decision latitude, low social support, high psychological demands, effort-reward imbalance, and high job insecurity [42]. Another finding, of particular interest to the present study, is a statistically significant relation between baseline job dissatisfaction and subsequent usage of psychiatric prescription drugs in a recent sample of 40-60 year old employees of the City of Helsinki [43].

Job satisfaction does not measure the work environment directly. It has, however, been shown to be highly dependent on the psychosocial work environment. The COPSOQ scales on demands, influence and development, interpersonal relations, and leadership explained 59% of the variation in job satisfaction, in a sample of employees in Germany 2004 [44]. Further, a meta-analysis based on 485 studies suggested that job satisfaction, with an overall correlation of 0.37 across four health outcomes, was an important factor influencing the health of workers [45].

Unfortunately, the questions and response categories that deal with psychosocial dimensions differ between our questionnaires to a degree that make it impossible to obtain any psychosocial measure that stays the same in all of the datasets. The questions and response categories for job satisfaction and job insecurity remained, however, unchanged throughout the questionnaires of DWECS 1995, 2000, and 2005, and this subset of the data is large enough to make a sensitivity analysis meaningful.

We want to know how and to what extent we can expect our primary analysis to be influenced by uncontrolled differences

in the psychosocial work environment. We will address this issue with a sensitivity analysis, where we perform the working hour analysis on the above-mentioned subset of the data, both with and without control for job insecurity and job satisfaction. The following questions will be used: (1) "Are you worried about becoming unemployed?"; (2) "Are you worried about difficulties in finding a new job with your present qualification?"; and (3) "Are you satisfied with your job?". The questions on job insecurity (which could be answered with either "Yes" or "No") will be combined into one dichotomous variable. Participants who answered "Yes" to at least one of the two questions will be categorized as having job insecurity, while those who answered "No" to both questions will be categorized as not having job insecurity. Job satisfaction will be treated as a categorical variable in three levels: (1) "To a high degree"; (2) "To some degree"; and (3) "Only to a lesser degree" or "No, or only to a slight degree". The working time arrangement parameters will be estimated first with, and then without, control for job insecurity and job satisfaction. In all other respects, we will use the statistical model of the primary analysis.

Shift Work

The Effect of Shift Work on Health

We control for shift work in the primary, the auxiliary, and all of the secondary analyses. In doing so, we will automatically obtain parameter estimates that can be used to calculate rate ratios for psychotropic medicine as a function of shift work (fixed night shifts or rotational shift work schedules vs other). To our knowledge, the prospective relationship between shift work and psychotropic medicine has never been studied in a general working population. Hence, the effect of shift work will be of interest, not only as a control variable, but also as a potential contribution to the body of knowledge on "shift work and health". In our opinion, the data material, inclusion criteria, significance levels, and statistical models that we use to estimate effects of long working hours are appropriate also for the estimation of shift work effects. Moreover, the primary statistical power is sufficient and the exposure is stable enough to make such an effort worth the while (see below). We will therefore publish results on shift work in addition to the ones on long working hours.

Transitions Between Work-Schedule Categories

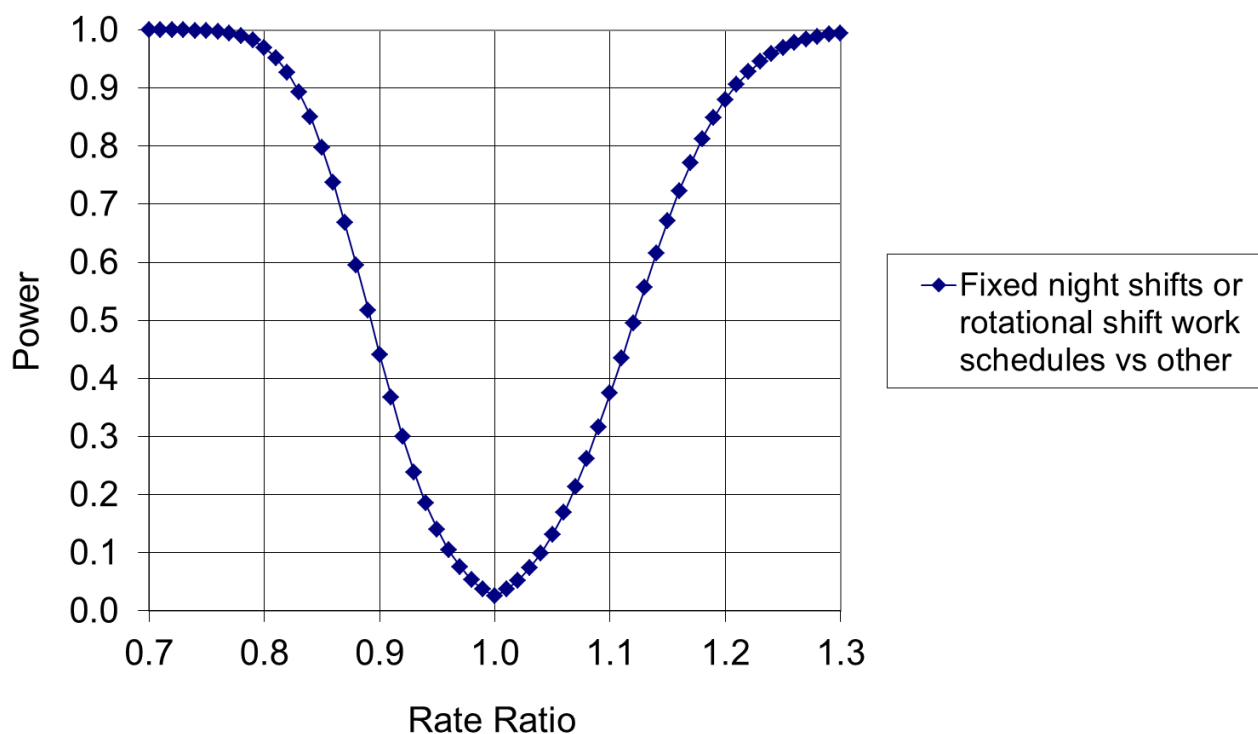
We used DWECS data to cross-tabulate an employee's work schedule category in 2000 with that in 2005. We included all who were economically active and 30 years or older in both waves. More than half (55.1%) (113/205) of the workers with shift work and 90.90% (1858/2044) of the workers with nonshifting work hours in 2005 had the same type of work schedule five years earlier, while 37.8% (113/299) of the workers with shift work and 95.28% (1858/1950) of the workers with nonshifting work hours in 2000 had the same type of work schedule five years later. Cohen's kappa for agreement between the work schedule category in 2000 and in 2005 was 0.38 (95% CI 0.32-0.44), which indicates fair agreement according to Landis and Koch [36].

Power Calculations for the Shift Work Hypothesis

According to DWECS 2000, 14.4% of the ones who worked 32 or more hours per week were either on fixed night shifts or rotational shift work schedules. We applied this information to

the data and assumptions we used in the power calculation for the primary analysis and calculated the statistical power to detect a contrast between fixed night shifts or rotational shift work schedules on one hand, and nonshifting nonnight work on the other (Figure 2 shows this contrast).

Figure 2. Power of detecting differences in psychiatric morbidity rates in Denmark, between employees on fixed night shifts or rotational shift work schedules and employees with other work schedules, as a function of the true rate ratio.



Results

The publication of the present study protocol ends the design phase of the project. In the next phase, the questionnaire data will be forwarded to Statistics Denmark where they will be linked to data on deaths, migrations, socioeconomic status, and redeemed prescriptions for psychotropic medication. We expect the analysis to be completed by the end of 2014 and the results to be published mid 2015.

Discussion

The Research Project

This protocol gives a detailed plan for a research project aimed at investigating the possibility of a prospective association between weekly working hours and use of psychotropic medication in the general working population of Denmark. We have shown that the statistical power is sufficient, and that the exposure is stable enough to make the study worth the while. We have also designed an auxiliary study, which will help us to interpret the results of the primary analysis, which, a priori, might be affected both by differences in morbidity and differences in propensity to seek treatment.

The presented study will utilize the work hour categories proposed by Kleppa et al [19], that is, 32-40 to represent normal

weekly working hours, 41-48 to represent overtime work which lies within the limits of the European working time directive, and 49-100 to represent overtime work beyond the threshold of the directive. These cut-off points will enable us to evaluate the results from a societal (national burden of disease) perspective, since they allow us to answer the following questions, "Are there important differences between the average rate among people with normal working hours, and that among people with overtime work within and beyond the EU directive, respectively?". The span of the maximum work hour category complicates, however, the interpretation of the results from an individual perspective. A null finding, which would indicate that the effect is unimportant from a societal perspective, does not necessarily mean that it is safe to work, for example, 60 hours or more per week. From this viewpoint, we understand that an extra work hour category would be of interest, especially to people in nations where it is normal to work 50 hours (or more) per week. An extra category would, however, reduce the statistical power of the analysis, and we prefer to have one sufficiently powered category (> 48 hours), instead of two underpowered categories (eg, 49-59; ≥ 60 hours).

Since our goal is to obtain statistical certainty, we choose to base our primary case definition on the aggregate of all types of psychotropic medicine, rather than performing analyses on particular types. It makes sense to do so. Anxiety disorders are strongly and positively correlated with depressive disorders

[19,22], and sleeping disorders are strongly and positively correlated with both anxiety and depressive disorders [46]. Based on a linkage between the ECM and the National Prescription Registry, 95.83% (75,815/79,117) of all new cases of psychotropic medicine use among employees in Denmark in 2001 concerned a drug in the category anxiolytics (33.26%, 26,315/79,117, of all cases), antidepressants (30.50%, 24,131/79,117, of all cases), or hypnotics and sedatives (32.07%, 25,369/79,117, of all cases).

It also makes sense to control for gender, age, socioeconomic status, and shift work. It is well established that women are treated for depression [47], anxiety [48,49], and insomnia [50] more often than men and that the occurrence of these diagnoses varies with age [47,49,50]. It is also well established that socioeconomic status is negatively correlated with mental illness; the lower the SES, the higher the rate of illness [51]. Shift work may induce the so-called shift work sleep disorder, and it is possible that such a condition will be treated with hypnotics as well as wakefulness-promoting drugs [52].

Study Strengths and Weaknesses

Since the clinical endpoint of the study is determined through national registers, which cover all residents of Denmark, and we are able to censor for deaths and emigrations, we have eliminated bias from missing follow-up data. The study is further

strengthened by its prospective design, the exclusion of prevalent cases and the use of a study population that has been randomly sampled from the target population. Another advantage is that all hypotheses and statistical models are completely specified, peer reviewed, and published before we merge the questionnaire data to the registers.

Nonrespondents in the baseline interviews weaken the study. Since long working hours imply less time to answer questionnaires, the response rates as well as the reasons for nonresponse might differ between the exposed and the unexposed workers. Selection bias cannot be ruled out. We believe, however, that any such bias will be mitigated through the exclusion of prevalent cases. Another weakness is the lack of adequate information on sleeping habits at baseline. As mentioned in the Introduction, one of the main theoretic reasons for an adverse effect of long working hours is its association with short sleep, which in turn is a predictor of mental disorders. If there were an effect of long working hours on mental health, then it would have been interesting to know to what extent this effect could be attributed to sleeping habits.

The study is not a randomized controlled trial, and can therefore not confirm etiological hypotheses. It may, however, confirm that long working hours is a predictor for incident use of psychotropic medicine, and if so, it will lend support to the hypothesis of a causal relationship.

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Authors' Contributions

HH provided the statistical expertise and prepared the first draft of the manuscript. KA provided the psychological expertise, and contributed in a critical revision.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The wording (in Danish) of the questions used to obtain information on working hours and work schedules.

[[PDF File \(Adobe PDF File\), 36KB - resprot_v3i3e51_app1.pdf](#)]

Multimedia Appendix 2

The wording (translated from Danish) of the questions used to obtain information on working hours and work schedules.

[[PDF File \(Adobe PDF File\), 35KB - resprot_v3i3e51_app2.pdf](#)]

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Abbreviations

ATC: Anatomical Therapeutic Chemical
COPSOQ: Copenhagen Psychosocial Questionnaire
CPR: Central Person Register
DANES: Danish National Working Environment Survey of 2008
DISCO: Danish version of the International Standard Classification of Occupations
DNPR: Danish National Prescription Registry
DWECS: Danish Work Environment Cohort Study of 1995, 2000, 2005, and 2010
ECM: Employment Classification Module
MHI-5: mental health inventory
NRCWE: National Research Centre for the Working Environment
OR: odds ratio
PYRS: person years at risk
SES: socioeconomic status

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Original Paper

Intervention Use and Action Planning in a Web-Based Computer-Tailored Weight Management Program for Overweight Adults: Randomized Controlled Trial

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Abstract

Background: There are many online interventions aiming for health behavior change but it is unclear how such interventions and specific planning tools are being used.

Objective: The aim of this study is to identify which user characteristics were associated with use of an online, computer-tailored self-regulation intervention aimed at prevention of weight gain; and to examine the quality of the goals and action plans that were generated using the online planning tools.

Methods: Data were obtained with a randomized controlled effect evaluation trial in which the online computer-tailored intervention was compared to a website containing generic information about prevention of weight gain. The tailored intervention included self-regulation techniques such as personalized feedback, goal setting, action planning, monitoring, and other techniques aimed at weight management. Participants included 539 overweight adults (mean age 46.9 years, mean body mass index [BMI] 28.03 kg/m², 31.2% male, 11% low education level) recruited from the general population. Use of the intervention and its planning tools were derived from server registration data. Physical activity, fat intake, motivational factors, and self-regulation skills were self-reported at baseline. Descriptive analyses and logistic regression analyses were used to analyze the results.

Results: Use of the tailored intervention decreased sharply after the first modules. Visiting the first tailored intervention module was more likely among participants with low levels of fat intake (OR 0.77, 95% CI 0.62-0.95) or planning for change in PA (OR 0.23, 95% CI 0.05-0.97). Revisiting the intervention was more likely among participants high in restrained eating (OR 2.45, 95% CI 1.12-5.43) or low in proactive coping skills for weight control (OR 0.28, 95% CI 0.10-0.76). The planning tools were used by 5%-55% of the participants, but only 20%-75% of the plans were of good quality.

Conclusions: This study showed that psychological factors such as self-regulation skills and action planning were associated with repeated use of an online, computer-tailored self-regulation intervention aimed at prevention of weight gain among adults being overweight. Use of the intervention was not optimal, with a limited number of participants who visited all the intervention modules. The use of the action and coping planning components of the intervention was mediocre and the quality of the generated plans was low, especially for the coping plans. It is important to identify how the use of action planning and coping planning components in online interventions can be promoted and how the quality of plans generated through these tools can be improved.

Trial Registration: Netherlands Trial Register: NTR1862; <http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1862> (Archived by WebCite at <http://www.webcitation.org/6QG1ZPIzZ>).

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KEYWORDS

behavior change; obesity; health promotion; intervention research

Introduction

Overview

Considering the lack of effective long-term treatments for obesity, prevention of obesity is very important [1,2]. This can be achieved by prevention of weight gain. This is particularly important among people who are overweight (body mass index [BMI] 25-30 kg/m²) because they are most at risk of becoming obese. The Internet may be a relevant medium to reach the large group of overweight people.

The Internet is increasingly being used as a channel for the delivery of interactive and individualized interventions to promote healthy lifestyles among various populations [3-6]. Such interventions can be effective at improving a variety of behaviors and outcomes [7-10], especially when a planning tool is included [11]. However, a large body of evidence suggests that the use of online interventions is often low [12-14]. In this paper, we focused on the use of GRIPP, which is an online computer-tailored self-regulation program aimed to prevent weight gain among overweight (BMI 25-30 kg/m²) adults [15]. The computer-tailored intervention consisted of 4 modules that people could visit in a 4- to 8-week period. Although this intervention did not show an additional effect over generic information as far as improving BMI, waist circumference, skinfold thickness, physical activity, and dietary intake, this result may in part be due to implementation failures. Various authors have suggested that process evaluations aimed at studying the efficacy of the implementation process are vital to optimize interventions and to ensure an actual effect (eg, [16]).

Similar to the GRIPP study [17], a steep decline in numbers of visitors to follow-up sessions is often observed, and nonoptimal use or exposure to the intervention content may result in an underestimation of the effects that can be achieved with an online intervention [18]. More evidence is needed with regard to implementation factors that may be associated with intervention use [16,19], such as dose and fidelity [12,18,20]. Using the GRIPP study, we systematically examined two implementation aspects. The first aim was to identify factors that are associated with first and repeated use of an online weight gain prevention program for overweight adults (ie, dose delivered). The second aim was to increase insight into the amount and quality of use of the planning tools in the online interventions (ie, fidelity).

Determinants of Intervention Use

To understand the potential impact that an intervention may have, it is important to understand who is reached by the intervention, when people are likely to engage in intervention activities and continue engaging in these activities and the extent to which the intervention is used as planned. Such factors may help to understand program implementation (failure) as well as ways to improve the quality of implementation [16,19].

The existing literature suggests that intervention use may be related to individual (ie, age, sex, education, BMI), motivational,

and behavioral factors. Older adults were more likely to use online interventions [12,14], and women [12-14] have been found to be more likely to use online interventions, but the evidence is inconclusive with respect to the level of education. Visiting and revisiting an online intervention may be related to risk factors such as higher-than-recommended intake of saturated fat [12], elevated cholesterol level [13], and higher [14] or lower body weight [12]. Thus, several studies examined the use of online interventions, but the results were inconclusive. Furthermore, little is known about the influence of psychological traits. Therefore, the possible influence of psychological traits, such as weight locus of control, restrained eating, and self-regulation skills, in addition to more traditional predictors on online intervention use were studied.

The present intervention was developed based on the principles of self-regulation theory [21-23]. Key processes in self-regulation are goal selection, action (planning), and evaluation. Such an intervention may have more appeal to people who already embrace the concept of self-regulation because it fits them better. Furthermore, self-regulation skills, including planning and coping, may decrease the intention-behavior gap and increase the likelihood of actual performance of a desired behavior (eg, [24,25]). However, self-regulation skills are likely to be a generalized concept, indicating that people with more self-regulation skills for health-related behaviors may also be better at planning to visit or revisit an intervention, because this is also an example of behavior regulation. Therefore, we hypothesize that those high in baseline self-regulation skills are more likely to visit and revisit the intervention.

There are two other important factors that influence weight-related behavior and may also influence intervention use: weight locus of control and restrained eating. Weight locus of control refers to perceived control of one's body weight. People who lack a feeling of control have been found to have less confidence in weight loss behaviors and a lower behavioral intention. Moreover, higher control is positively related to picking up weight loss ideas from an earlier intervention [26]. Therefore, we hypothesize that participants with a high locus of control are more likely to visit and revisit the intervention. For those with a more external locus of control, the intervention is probably less interesting, as they may not believe that it is possible to regulate their own behavior.

Previous studies have shown that restrained eating can be related to weight-related outcomes and participation among obese participants [27]. We hypothesize that restrained eaters are more likely to visit and revisit the intervention because they will use the opportunity to improve their control over their (eating) behavior and weight. A self-regulation intervention may thus be extra attractive to them.

Quality of Use: Action and Coping Planning

Self-regulation often starts with goal selection—determining what one wants to achieve. This goal is the reference point for all other related activities, such as monitoring progress of

behavior change toward the goal [22]. However, to serve as a useful reference point, the goal must be very specific (eg, indicating what will be done at what time). Action planning specifies where, when, and how to act [28]. Coping planning (ie, linking anticipated risk situations with a suitable coping response) is a recurring event in self-regulation, because it allows the person to adapt his or her behavior to change or unfavorable circumstances [23,25]. Therefore, goal selection, action planning, and coping planning were important intervention components [29-31]. Studying the use of these tools will tell us more about the fidelity of implementation of these tools [16].

Because action plans must be of good quality to be effective [32], we aimed to study the use and quality of the goals and plans made by the participants [11]. In this trial, a guided, open format was chosen. Insight into the quality of plans generated through this type of planning tool is highly relevant because it can help to improve online self-regulation interventions.

This trial aimed to answer two questions: (1) Which baseline demographic, psychological factors, behavioral factors, and self-regulation skills are associated with first time and repeated use of an online computer-tailored self-regulation intervention aimed at preventing weight gain among overweight adults? (2) Do participants use the guided, open format tools for action planning and coping planning, and if so, what is the quality of the generated plans?

Methods

Design, Participants, and Recruitment

The data for this study were generated in a randomized trial (NTR1862) to establish the effects of the intervention on anthropometric and behavioral outcomes. More information about this trial can be read in van Genugten [17]. In this trial, the tailored intervention website was compared to a generic information website. For this study, only data from the tailored intervention website was used. Anthropometrics and self-reported behavior were assessed at baseline and 6 months after the intervention.

Participants were recruited from the general population through advertisements placed in local newspapers and flyers that were distributed door-to-door, in the waiting rooms of general practitioners and among the employees of four large companies. Participants enrolled in the study by filling out an online submission form. Subsequently, criteria for inclusion (25-60 years of age, BMI 25-30 kg/m², ability to read and write in Dutch, and easy access to the Internet) and exclusion criteria (pregnancy, following a diet prescribed by a dietician or physician, having a history of depression or eating disorder) were used. In total, 630 people completed the online registration, and 516 initially participated by completing the baseline questionnaire and/or coming in for anthropometric measurements (n=480). Two hundred sixty-nine participants were allocated to the tailored intervention group and were included in this trial.

Procedures

After subscription, participants received a confirmation letter and information leaflet about the trial. They also received an email in which they were asked to fill out the online baseline questionnaire (motivational factors, dietary intake, physical activity, and self-regulation skills). Weight, height, waist circumference, and skinfold thickness were measured at the hospital site where they also filled out the informed consent form. Participants preferably completed both measurements (anthropometrics and questionnaire) but were randomized even if they had completed only one measurement.

All randomized participants received a login name and password by email to access their assigned intervention program. Participants were asked to (re)visit the website at least 3 or 4 times during a 2-month period. They received biweekly email reminders to (re)visit the intervention website. Six months after completion of the intervention period, participants were asked by email to fill out the online questionnaire again and their anthropometrics were assessed at the hospital site. Phone calls were made to participants who did not respond by email. Participants who filled out the questionnaire and had their anthropometrics measured at the 6-month follow-up received a gift voucher of €10 (US\$13.65).

The Intervention

Tailored Intervention

The intervention's main objective was to prevent weight gain in overweight adults by inducing small changes (100 kcal/day) in energy balance-related behaviors. Examples of these changes include increasing the frequency and duration of physical activity and reducing the intake of calories from several categories, such as dairy, meat, cheese, sauce and gravy, snacks, and sweetened drinks [33]. The intervention goals, methods, and strategies were based on self-regulation theory [22], motivational theories [28,34,35], and goal-setting and action-planning theories [28,36].

The intervention consisted of 4 modules. To deliver the self-regulation strategies in a timely fashion, each module was to be visited one week after the previous one, guiding the participant through all steps of self-regulation (goal setting, active goal pursuit, and evaluation [22]). Completion of all modules would take about 90 minutes. The first module aimed at increasing participants' commitment to prevent weight gain by first asking them to weigh the pros and cons of weight gain prevention, and to choose one behavior change and plan for that change. The second and third modules evaluated progress on behavior change by giving participants feedback on their performance during the previous week, based on self-reported behavior change. If necessary, the intervention supported adaptation of the action and coping plans (when the participants failed to achieve the behavioral goals). The 4th module instructed participants on how to maintain self-regulation of body weight without using the program and they were provided with a tool to monitor and evaluate changes in their body weight. Modules 1, 2, and 3 are each supposed to be used at least one week apart. As they use the modules, participants fill in their body weight every week. When using the 4th module, a graph

is made, showing the weight development of the participants. Furthermore, written feedback is provided. Both the graph and feedback show the normal weight range of the participants (taking daily and weekly fluctuations into account), indicating when weight is actually gained or lost. To conclude the program, the participants sign a personalized contract, which includes the goals and plans they had written down in the intervention, as well as their weight status and information for weight regulation in the future.

The tailored modules were embedded in a website that also contained recipes, a peer-to-peer forum, and links to useful websites. Reminders to (re)visit the intervention were sent to the participants every two weeks. A more detailed description of the intervention's contents can be found elsewhere [15]. Visuals of the intervention can be found in [Figure 1](#), [Figure 2](#), and [Multimedia Appendix 1](#).

Figure 1. Goal setting and action planning in the GRIPP intervention.



Figure 2. Coping planning in the GRIPP intervention.

GO!

Wat kunt u nog doen om goed voorbereid te zijn op uw kleine verandering?

Een goede voorbereiding verhoogt uw kans op succes. bedenk daarom of u helemaal klaar bent om aan de slag te gaan met uw kleine verandering. U gaat bijvoorbeeld een lijstje maken met de spullen die u nog in huis moet halen (zoals gezonde producten), nadenken over of u bij het maken van uw kleine verandering steun wilt van familie of vrienden, en uzelf alvast voorbereiden op moeilijke situaties.

Wij kunnen u helpen om goed voorbereid aan de slag te gaan aan de hand van een drietal stappen. De stappen die u dan heeft doorlopen kunt u op het einde, in de vorm van een voorbereidingsplan, afdrukken.

VOORBEREIDING OP HET DOEN

```

graph LR
    S1((STAP 1)) --> B1[Maak een lijst met behoeftes]
    B1 --> S2((STAP 2))
    S2 --> B2[Bedenk hoe en door wie u wilt worden gesteund]
    B2 --> S3((STAP 3))
    S3 --> B3[Bereid u voor op moeilijke situaties]
  
```

Bij welke stappen wilt u graag hulp van dit programma?

1. Leren hoe u kunt bepalen of een product gezond is zodat u een lijst met behoeftes kunt maken
 - Ja
 - Nee
2. Bedenken hoe en door wie u gesteund wilt worden
 - Ja
 - Nee
3. Uzelf voorbereiden op moeilijke situaties
 - Ja
 - Nee

Action Planning

Based on the tailored feedback on dietary intake (DI) or physical activity (PA), people were guided in choosing what they wanted to change (goal setting) and where, when, and how to make the change (action planning) in an open format. The guided, open format was chosen to allow for personal preferences, which is important for motivation [37]. Moreover, this format was supposed to lead to very specific goals and plans. Such goals and plans usually have a positive influence on perceived behavioral control [38].

To establish a goal, people could first choose a category of change (eg, sweetened drinks or snacks) in which the feedback indicated that improvement was possible. Then, more specific feedback was provided on possible changes within the category. For example, first they could choose to decrease their snack intake. In the next step, they could choose what they want to eat (eg, fewer chocolate bars or salty snacks like peanuts). Participants were encouraged to choose a change that they would like to make and feel high self-efficacious about. Finally, participants had to fill out the content of the change, size of the change (eg, number of minutes of PA) and, if necessary, decide on an alternative (eg, eat an apple instead of a candy bar) to

translate their goal into an action plan. For example, a correct action plan might be “If I have breakfast, I will eat 2 sandwiches (size) with nonfat cheese instead (alternative) of normal cheese (content).”

Coping Planning

To prevent relapse in the first week of change, people were asked whether they expected to encounter a risk situation (a situation in which they expected that making the change might be difficult; eg, at a party). If they did, they were asked to think about this situation and to describe their (coping planning) strategy to avoid or handle the situation. They could write down their strategy in text boxes [39] in a guided, open format. Together, the description of the situation and the strategy resulted in an implementation intention [38]. An example of a good coping plan would be “If my colleagues are eating pie and offer me a slice, I will say no and eat an apple.”

Dependent Measures

Intervention Use

An objective measure of intervention use was obtained by retrieving the log-in data from the intervention server registrations, which registered how often each participant logged

in to the program and which intervention modules they visited (0-3 for generic information, 0-4 for tailored intervention). First, a dichotomous “never-ever” score was created, with 0 indicating “never visited” and 1 indicating “visited at least once” (sum score >1). For those who visited at least 1 module (sum score >1), a dichotomous score was made for “revisiting” (visited first module only: 0, also visited later modules: 1). This categorization was based on the 3 steps of intervention use as defined by Brouwer et al [12,20]: landing at a website, visiting a website, and coming back for a second visit.

Use of Action-Planning and Coping-Planning Components and Quality of Goals and Plans

Information about the use of the action-planning and coping-planning components and the quality of the plans developed by the participants was also obtained from the intervention server registration, where the plans that had been written were stored. Two dichotomous variables were made, indicating whether people chose to make a change in dietary intake and/or physical activity. A dichotomous variable was created for use of the action-planning component (0: no plan, 1: a plan). Then, the quality of the goal was determined by scoring the text that was written in the text boxes in the program. For this text, 1 point was obtained if a challenging but realistic goal was stated (eg, increase walking by 30 minutes daily) and 1 point was obtained if the situation in which the change would be made was clearly and realistically stated (eg, when going to and returning from work). For PA, a third point could be obtained for filling out with whom one was planning to do the activity (eg, with my partner or alone). Therefore, 3 points could be obtained for a stated PA goal, and 2 points could be obtained for a DI goal.

A similar approach was used for use and quality of the coping plans, in particular how the participant planned to avoid or cope with a difficult situation in the first week of behavior change. A dichotomous variable was created based on the participant’s use of the coping-planning component (0: did not describe a coping plan, 1: described a coping plan). Next, the content of the coping plan was coded to assess its quality. A coping plan was coded as correct (scoring a 2) if a response was given that (1) would facilitate the desired behavior, and (2) was feasible in the risk situations that were defined [40]. If either or both of these criteria were not met, one point was given to indicate an incorrect plan.

All goals and coping plans were coded by 2 researchers (LVG and HVDP) separately, and then discussed until agreement was obtained.

Independent Measures

Motivational Variables

Intention to prevent weight gain, perceived behavior control, weight locus of control, and restrained eating are potential determinants of intervention use and were assessed by online self-report at baseline. A description of the assessments of these factors is described in [Multimedia Appendix 2](#).

Weight locus of control was assessed using a translation of the Weight Locus of Control scale [41], which has 4 statements

(two externally and two internally oriented items). Factor analyses showed that only one factor could be identified. The scale reliability (Cronbach alpha) of the four items was 0.61, which is low, but comparable to the original scale [41]. Thus, a composite measure (mean value) was created.

Restrained eating was assessed with the restrained subscale of the Dutch Eating Behavior Questionnaire [42,43]. This questionnaire consists of 10 items about restrained eating. Cronbach alpha of all items was 0.87 and all items were combined to one mean value.

Self-Regulation Skills

Because monitoring weight, planning for PA, planning for DI, and proactive coping skills could be related to the participant’s use of the intervention, these can be considered intervention outcomes. These variables were assessed by self-report at baseline and at the 6-month follow-up. A description of the assessments of these factors is provided in [Multimedia Appendix 2](#).

A dichotomous variable was made for monitoring of weight: weighing weekly (1) and not weighing weekly (eg, daily or never; 0).

Planning for PA was assessed with 4 items and planning for DI was assessed with 3 items. Cronbach alpha was 0.92 for planning for PA and 0.94 for planning for DI. Therefore, composite measures (mean scores) were calculated for PA and DI, respectively.

Proactive coping skills toward body weight were measured using the 21-item Proactive Competence Scale [44], which is based on the 5 phases of coping: (1) resource accumulation, (2) recognition of potential stressors, (3) initial appraisal, (4) preliminary coping efforts, and (5) elicitation and use of feedback concerning initial efforts [45]. All items were combined into one mean score, which had a Cronbach alpha of 0.92.

Fat Intake and Physical Activity

Fat intake and physical activity were assessed by self-report at baseline and 6 months after the intervention.

Fat intake was assessed using a food frequency questionnaire that assessed the frequency and quantity of a variety of high-energy food eaten in the past week. It was based on a Dutch validated questionnaire [46], and it enabled the researcher to calculate fat intake in fat points. The questionnaire consisted of 74 questions and was organized according to meal pattern. Participants recorded their frequency of consumption and portion size for a selection of food items eaten during meals or between meals. Higher scores indicate more frequent and/or larger amounts of fat intake. There were 23 products that fell into the following categories: dairy products (5), butter (1), gravy (1), sandwich fillings (3), meat and cheese for main dinner (2), and sweet, salty, hot and cold snacks (11 in total). In total, a maximum of 83 fat points could be obtained.

Physical activity was assessed using a questionnaire based on the Dutch validated Short Questionnaire to ASsess Health-enhancing physical activity (SQUASH, developed to

assess habitual physical activity) [47]. In this 16-item questionnaire, participants were asked to indicate how many days of the week they participated in specific activities and how much time they engaged in the activity per occasion. For active transport, respondents were asked how often they cycled and walked from home to work, and the duration. The same questions were asked about walking and cycling during leisure time. Furthermore, participants were asked how many different sports they did on a weekly basis (with a maximum of 4). For each different sport, they were asked to pick their sport activities (eg, swimming, running, soccer) from a list, indicating the weekly frequency and the average time they engaged in that activity per occasion. For each category, the mean number of minutes per day was calculated by multiplying the frequency with the duration and dividing this number by 7. Next, the total number of minutes engaged in physical activity per day was calculated as the sum of all activities (active transportation, leisure time activities, and sports).

Body Mass Index

The body measurements were performed by trained research assistants, following a measurement protocol. Participants' height was measured twice at baseline using a Seca mobile height rod with an accuracy of 0.1 cm. The mean of both measures was used for height. A calibrated electronic digital floor scale (Seca 888 class III) was used to measure body weight, with an accuracy of 0.2 kg. The measures of height and weight were used to calculate BMI (weight [kg]/height [m]²). Body weight was measured at baseline and 6 months after the intervention period.

Sociodemographic Factors

Sex (male/female), date of birth, and educational level were assessed in the baseline questionnaire. To determine age, we asked participants their date of birth. Education was assessed

by asking the participants to indicate what their highest completed level of education was (choosing 1 of 8 options). A 3-category variable was subsequently made, indicating a low (completed no education, primary school, secondary school, or lowest level of high school or lower vocational training), medium (completed intermediate or high level high school), or high (completed higher vocational training, college or university) level of education.

Analyses

Descriptive statistics were used to describe the study population in terms of baseline demographic, behavioral, and psychological factors. Logistic regression analyses were applied to study participant predictors of first intervention visit and follow-up visits (dependent variables). To identify the best predictors of use, a backward elimination (likelihood ratio) procedure was used. Independent variables were age, education, sex, BMI, fat intake, physical activity, intention, and perceived behavioral control for weight gain prevention, weight locus of control, restrained eating, monitoring of weight, action planning for change in DI and PA, and proactive coping skills as assessed at baseline.

Descriptive statistics were used to describe the use of the self-regulation components and the quality of the participants' plans.

Results

Study Population

The mean age of the participants was 47.7 years (SD 9.2), 31.3% (84/269) were male, 10.3% (24/232) had a low level of education, and 48.7% (113/232) had a medium level of education. The mean BMI was 28.1 kg/m² (SD 2.02; [Table 1](#)).

Table 1. Baseline characteristics of the study participants.

Characteristics	Values
Demographics^a	
Age (years), mean (SD)	47.7 (9.2)
Male, n (%)	84/269 (31.2)
Education level, n (%)	
Low	24/232 (10.3)
Medium	113/232 (48.7)
High	95/232 (40.9)
Outcome measures	
BMI, kg/m ² , mean (SD)	28.17 (2.02)
BMI, n (%)	
Healthy weight	9/224 (4.0)
Overweight	169/224 (75.4)
Obese	46/224 (20.5)
Fat intake, points, mean (SD)	17.02 (6.0)
Physical activity, minutes, mean (SD)	63.1 (50.4)
Motivational factors^b	
Intention for weight gain prevention, score (SD)	4.71 (0.6)
Perceived behavioral control for weight gain prevention, score (SD)	4.3 (0.8)
Self-regulation factors	
Weekly monitoring weight, n (%) ^c	112/230 (48.7)
Action planning, ^c mean (SD)	
DI	2.30 (1.0)
PA	2.08 (1.0)
Proactive coping skills, ^c mean (SD)	2.67 (0.5)
Weight locus of control, ^c mean (SD)	3.76 (0.66)
Restrained eating, ^b mean (SD)	3.11 (0.63)

^aN values are based on number of respondents.

^bScore range 1-5.

^cScore range 1-4.

Intervention Use

The first intervention module was visited by 93.3% (251/269) of the participants (Figure 1), the second by 74.1% (199/269), the third 26.7% (71/269), and the fourth and last module by 15.2% (40/269). The mean number of visits was 1.8 and the median was 1. Logistic regression analysis (Table 2) showed that those with a lower level of physical activity (odds ratio

[OR] 0.98, 95% CI 0.96-0.999), lower action planning for PA (OR 0.23, 95% CI 0.06-0.9) and lower fat intake (OR 0.77, 95% CI 0.62-0.95) at baseline were more likely to visit the intervention once.

Those with low proactive coping skills (OR 0.28, 95% CI 0.10-0.76) and high levels of restrained eating were more likely to revisit the intervention (OR 2.45, 95% CI 1.11-5.43).

Table 2. Results of multivariable backward logistic regression analyses examining potential correlates of use and repeated use of the tailored intervention (N=269).

Predicting factors	Using the intervention at least once	Using the intervention at least twice
	OR (95% CI) ^a	OR (95% CI)
Demographic factors		
Age (years), mean (SD)	-	-
Sex		
Male	-	-
Female	-	-
Education level		
Low	-	-
Medium	-	-
High	-	-
BMI and behavioral factors		
BMI, kg/m ²	-	-
Fat intake, mean fat points/day	0.77 (0.62-0.95)	-
Physical activity, mean minutes per day	0.98 (0.96-0.999)	-
Motivational factors^b		
Intention for weight gain prevention, mean	-	-
Perceived behavioral control for weight gain prevention, mean	-	-
Self-regulation factors		
Monitoring weight		
Nonweekly	-	-
Weekly	-	-
Action planning,^c mean		
DI	-	-
PA	0.23 (0.05-0.97)	-
Proactive coping skills for prevention of weight gain, ^c mean	-	0.28 (0.10-0.76)
Restrained eating, ^b mean	-	2.45 (1.12-5.43)
Weight locus of control, ^c mean	-	-

^aDashes indicate that the specific factor was not included in the final logistic model. In the last column, the last model with only statistically significant correlates is presented.

^bScore range 1-5.

^cScore range 1-4.

Use of Planning Components

Server registrations showed that 140 (55.7%) of the participants chose to make a change in DI and 40 (15.9%) chose to make a change in PA; the other participants did not set a goal. Furthermore, 138 participants (54.9%) wrote an action plan for change in DI (Table 3), 111 (44.2%) of whom had a plan of good quality (clear description of situation and good plan). An action plan for an increase in PA was developed by 39 people (15.9%); 14 (5.6%) stated a plan of good quality. The most common reason for a plan to be considered of poor quality was

that it gave an unclear description of the moment of change (eg, in the morning).

In total, 70 people (27.9%) indicated that they were expecting a risk situation for making a change in DI. A clear and helpful coping plan (clear description of high-risk situation and supportive coping plan) was stated by 50 (19.9%) participants, 12 participants (4.7%) were expecting a high-risk situation for a change in PA, and 6 of them (2.3%) wrote a clear and helpful coping strategy. Plans were deemed insufficient because they had either an unclear description of the situation or an unhelpful strategy.

Table 3. Frequency of use of the self-regulation tasks and quality of the generated plans among participants who visited the first module of the tailored intervention.

Target behavior	Self-regulation component	Yes ^a n (%)	Good quality n (%)
Visit intervention	Visit first tailored module	251 (100)	-
Dietary intake			
	Chose a change in DI	140 (55.8)	-
	Set a goal for DI	138 (55.0)	111 (80.4)
	Described a coping plan for a change in DI	70 (27.9)	50 (71.4)
Physical activity			
	Chose a change in PA	40 (15.9)	-
	Set a goal for PA	40 (15.9)	14 (35.0)
	Described a coping plan for a change in PA	12 (4.8)	6 (50.0)

^aThe third column refers to the percentage of participants that have used certain parts of the tailored intervention. The second column refers to the percentage of participants who had stated a goal or plan of good quality (ie, obtained 2 points by the coding procedure). A dash indicates no data.

Discussion

Overview

In this study, we examined the reach and predictors of reach of an online computer-tailored weight gain prevention intervention for overweight adults. Initial use of the intervention was high (93.3%, 251/269), but only 26.4% (71/269) of the participants visited 3 modules and 14.9% (40/269) completed all 4 modules. Use of the first tailored intervention module was more likely among participants who had a lower fat intake, lower physical activity, and lower action planning for PA at baseline compared to those who never visited the intervention. Repeated use of the intervention was more likely among participants with higher levels of restrained eating and who had a lower score on proactive coping skills at baseline. Of those who used the tailored intervention, 55.8% (140/251) stated a goal for a change in DI and 15.9% (40/251) for a change in PA. Only 27.9% (70/251) made a coping plan for DI and 4.8% (12/251) for PA. Approximately half of the written goals and plans were of good quality.

Website Reach and Characteristics of Users

Use of the first intervention module was high, 93.3% (251/269). However, only 15.2% (40/269) of all the participants finished the last (fourth) module. The modules required quite some effort because they were interactive and needed personal input for completion of questionnaires and formulation of action and coping plans. The sharpest decline in visits to the intervention was between the second and third visits. In the second visit, participants had to evaluate the success of their behavior change. It is possible that participants experienced this module as difficult, confrontational, or not supportive enough. The observed decline after the first module is comparable to what has been reported in evaluations of other online interventions [12-14,48], but is nevertheless worrisome. The email reminders sent every two weeks to (re)visit the intervention may have helped somewhat, but they were not sufficient to prevent the decline in follow-up visits. Other actions to increase revisiting might be helpful, for example, telephone calls or short initial

face-to-face contact [10,48]. Short text messages may also be beneficial. They have been shown to improve the effects of a planning intervention on fat intake [11]. Including text messaging would also be an effective way to remind participants of their personal goals and plans, which is effective in increasing brisk walking [49].

This study showed that trait-like psychological factors, including body weight self-regulation skills and restrained eating, might influence online intervention use even more than behavioral or demographic factors. Restrained eaters were more likely to revisit the intervention. Perhaps this is because some characteristics related to restrained eating, such as high conscientiousness [50], may increase one's intention to complete activities. Restrained eaters may also be extra motivated to find extra knowledge and strategies to control their dietary intake. Nonrestrained eaters may not be as motivated to complete the intervention. Perhaps they can be motivated in other ways, for example, by the promise of a self-introduced reward when finishing the program or achieving a goal.

Baseline weight-related proactive coping skills were negatively related to revisiting. This may indicate that those who could benefit most from the intervention (through learning planning and coping skills) were indeed more likely to use the intervention more often, whereas those who already had good coping skills may have felt that they were not sufficiently supported by the program. Therefore, the program may be adapted to fit the needs of those who already have good coping skills, but who have nevertheless not been successful in managing their weight.

Overall, these results indicate that self-regulation skills and traits that have previously been related to body weight have an influence on intervention-related behavior. As such, one must realize that choices that are made during intervention development (eg, theoretical framework and methods) may influence the motivation of certain groups to use the intervention. This is especially notable when looking at the differences between first and second time use; self-regulation

factors had stronger relations with second time use (continuing use after module 1) than first time use.

Reach of the intervention was not associated with motivational factors. This contradicts the findings of other studies [12,13,51] that found that more motivated participants were more likely to revisit. An explanation of this difference may be that the self-regulation tools in this intervention were incorporated in a comprehensively tailored program and that the tailoring resulted in also attracting and committing participants with relatively lower levels of motivation to visit and revisit the intervention website. However, it may also be a consequence of the overall high motivation among participants, with little variance. Thus, the precise relation between motivation for behavior change and intervention use needs more exploration. Furthermore, future research could also include other individual predictors, such as disinhibition, taste, impulse control, and weight-related self-esteem.

Use and repeated use were also not related to sociodemographic characteristics. This may indicate that the program was equally appealing to people with higher and lower educational levels.

Fidelity

More participants described a goal for change in DI compared to PA. This preference has been observed before in weight-related behavior studies [52-54]. Of the 269 participants, 66.9% (180) wrote down their behavior action plan, but the coping-planning component was used by only 30.5% (82/269). Similar figures have been reported in other online tailored interventions, for example by Spittaels and DeBourdeadhuij [48], who found that only 3 of 6 people used the goal-planning component for improving PA. The goal-setting and action-planning components required active involvement of the participants (eg, self-reflection, thinking about a solution, writing it down). A lack of use of the goal-setting component is worrisome because the behavior change goal is the starting point for the rest of the intervention and a coping plan is beneficial for actual change. Therefore, it is very important to identify how the use of action- and coping-planning tools in online interventions can be promoted.

To our knowledge, this is one of the first studies to investigate fidelity in terms of looking at the quality of goals and plan from an open-ended entry approach [11]. In general, the quality of the participants' action plans was higher than the quality of the coping plans. Coping planning is a more complex process than action planning and requires the identification of critical situations and then finding an appropriate and feasible solution [36].

The complexity of planning was also visible in another formative evaluation of a self-regulation intervention to promote PA among adolescents; it showed that participants often found it difficult to make detailed plans for a whole week [55]. Although the format in which participants plan certain activities in the first week is used by more interventions (eg, [56]), it may be too difficult to think this far ahead. Therefore, if the participant does not define a natural situation that is likely to be encountered (ie, situational cue), which was often the case in our study, the

process of automated cue response cannot take place [38]. Exercises that do provide planning with a situational cue to promote the self-regulation of behavior or health have been applied in many other studies (eg, [57-59]), and have been found to be effective in an obese population [11]. However, most of these studies used a closed-ended format or a more intensive approach, such as 10 weekly group sessions [57]. For example, Lee and colleagues provide their participants with a tailored plan to be physically active for 30 minutes at least 5 days a week [60]. There is also evidence that action plans that are completed in the presence of a counsellor are more strongly related to behavior change [61], but the presence of a counselor may not necessarily lead to increased self-regulation of diet and PA [62]. However, this may also be related to quality differences between counsellors, which may be present even when they are trained, have practiced, and have received feedback [63].

Furthermore, even though computer tailoring mimics individual counseling to some extent, this interaction may not apply to action- and coping-planning components. The low use of the planning elements and quality of the goals and plans may indicate that this is a difficult task for participants or that it requires too much effort, at least in the way these planning components were incorporated into the present intervention. It is, therefore, very important to identify how the use and quality of action and coping plans in online interventions can be improved.

Strengths and Limitations

One of this study's strengths is its use of objective information to assess the level of use of the website and the goal-setting and coping-planning tools. Additionally, we were able to link intervention use to personal characteristics, making it possible to describe characteristics of users and nonusers. Moreover, BMI was measured in an objective way. However, other correlates of intervention use were based on self-report, and it was not possible to compare the open-ended planning format to a closed-ended planning format. Finally, these results cannot be generalized to the whole population, because our participants were all overweight (BMI 25-30 kg/m²) and motivated to participate in this study.

Conclusions

This trial showed that psychological factors such as self-regulation skills and action planning were associated with repeated use of an online, computer-tailored self-regulation intervention aimed at prevention of weight gain among overweight adults. For future research, including a wider variety of variables that may be related to intervention use can provide more insight into the factors that are related to intervention use. Reach of the intervention was not optimal, with relatively few participants visiting all the intervention modules. The use of the action- and coping-planning components of the intervention was even lower and the quality of the generated plans was disappointing, especially for the coping plans. It is important to identify how overall reach of the intervention can be improved, as well as use and quality of action-planning and coping-planning components.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots from the GRIPP intervention, showing the steps of the tailored intervention.

[[PDF File \(Adobe PDF File\), 2MB - resprot_v3i2e31_app1.pdf](#)]

Multimedia Appendix 2

Description of measurements.

[[PDF File \(Adobe PDF File\), 63KB - resprot_v3i2e31_app2.pdf](#)]

Multimedia Appendix 3

CONSORT-EHEALTH checklist V1.6.2 [64].

[[PDF File \(Adobe PDF File\), 989KB - resprot_v3i2e31_app3.pdf](#)]

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Abbreviations

DI: dietary intake

PA: physical activity

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Original Paper

A Comparison of Tablet Computer and Paper-Based Questionnaires in Healthy Aging Research

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Abstract

Background: Digital questionnaire delivery offers many advantages to investigators and participants alike; however, evidence supporting digital questionnaire delivery via touchscreen device in the older adult population is lacking.

Objective: The objective of this study was to compare the use of tablet computer-delivered and printed questionnaires as vehicles for the collection of psychosocial data from older adults to determine whether this digital platform would be readily adopted by the sample, and to identify whether tablet delivery influences the content of data received.

Methods: The participants completed three questionnaires using both delivery methods, followed by a brief evaluation.

Results: A nonparametric one-sample binomial test indicated a significantly greater proportion of individuals preferred the tablet-delivered questionnaires ($z=4.96$, SE 3.428, $P<.001$). Paired sample t tests and Wilcoxon sign-rank tests indicated that measures collected by each method were not significantly different (all $P\geq.273$). Ease of use of the tablet interface and anxiety while completing the digital questionnaires were significantly correlated with preferences, ($r_s=.665$, $P<.001$ and $r_s=.552$, $P<.001$, respectively). Participants most frequently reported that the tablet delivery increased speed of use and improved data entry, although navigation was perceived as being more difficult. By comparison, participants felt that the paper packet was easier to read and navigate, but was slow and cumbersome, and they disliked the lack of dynamic features.

Conclusions: This study provides preliminary evidence suggesting that questionnaires delivered to older adults using contemporary tablet computers may be acceptable and do not substantively influence the content of the collected data.

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KEYWORDS

healthy aging; questionnaire; tablet computer; behavioral psychology

Introduction

Importance of Assessing Health-Related Quality of Life in Older Adults

The population of the United States is aging rapidly, and the number of adults 65 years of age or greater has increased more than 15% since the year 2000 [1]. Whereas life expectancy has increased, the onset of morbidity associated with advanced age

has not been substantially delayed, resulting in many individuals living with disease for a great number of years [2]. Researchers are therefore targeting this population in an effort to increase health-related quality of life (HRQL) and reduce the financial burden associated with a larger portion of the population living with disease.

Traditional Methods of Health-Related Quality of Life Assessment

The assessment of HRQL and health-related behavior is typically done by providing participants with paper and pencil questionnaires. For smaller sample sizes, this method is relatively inexpensive and can allow researchers to examine theoretical constructs that may underlie behavior change brought about by intervention. However, as sample sizes increase, this delivery method can become expensive, time and labor intensive, and the data are exposed at many points to the potential for human error [3]. Further, items may be left unanswered by the participant, and follow-up on these items, particularly those that are sensitive in nature, may be uncomfortable and perceived as coercive by participants.

The Potential Role of Technology in Questionnaire Delivery

Technological advances continue to generate new devices that, when used properly, may increase the efficiency and accuracy of questionnaire data collection. By delivering questionnaires digitally, researchers pay fixed costs initially (eg, development costs, equipment costs), and unlike paper-based questionnaires, these costs increase little with expanding sample sizes [3-5]. Digital questionnaire delivery provides several additional advantages: (1) data are able to be validated in real time, (2) prompts can be provided where necessary for completion of missing or unreasonable items, and (3) the need for a data-entry process is alleviated, removing another potential source of error.

The advantages of digital questionnaires over paper-based questionnaires are of little value if the intended audience reacts negatively to their use. Indeed, the rapid evolution of technology, particularly with regard to input styles and techniques, can make it difficult for some individuals to adopt new devices [6]. For example, for most of their adult lives, older adults were not exposed to computer technology. Most older adults were never employed in a position that required computer proficiency, nor trained in such skills [7]. For these individuals, Internet-based questionnaires delivered via personal computer (PC), which require the use of a mouse, keyboard, and Internet browser come with a steep learning curve [8-12]. Fortunately, advancements in tablet computer technology in recent years have produced devices that lessen these barriers. Tablet computers are equipped with sensitive touchscreens, resulting in a device that is more intuitive and interactive (ie, does not require an input device) [8,12,13]. Further, these devices typically do away with complicated menus and task bars, and this reduction in visual clutter is an important consideration when designing interfaces for older adults [9]. Such simplicity has likely driven increased rates of tablet computer adoption among older adults. Currently, in those 50-64 years of age, 27% now own a tablet computer, as do 13% of those greater than 65 years of age, an increase from 4% and 2% respectively in 2010 [14,15].

Results from the few interventions using tablet devices to positively influence health behavior in older adults have been promising [16-18]. For example, Silveira et al [17] delivered a 12 week exercise intervention to three groups of older adults: Two groups received a tablet-based goal setting and

self-monitoring application, and one tablet group received the intervention plus a social networking component. A third completed all study activities with printed materials. Those in the tablet-based groups demonstrated greater adherence and engagement with the program, and those who received the application with a social component were more likely to change their behavior than those who received the print-based materials.

These studies suggest that tablet computers can be used to effectively deliver content to older adults. However, the apparent feasibility of tablet-based questionnaire delivery within this population, and the potential advantages of doing so, do not provide a sufficient basis for the adoption of the technology in the research context. Similar concerns were expressed when Web-based, PC-delivered questionnaires initially increased in popularity. For example, several researchers examined whether mode effects existed for Web-based versus paper-based delivery of questionnaires [19-22]. Denscombe [19] conducted a direct comparison between Web-based and paper-based questionnaires delivered to teenage students, and found little evidence that a mode effect was present.

Because tablet computers are able to offer unique, minimally cluttered interfaces, and because they provide a unique method for interaction, it is important to determine whether these features result in improved or diminished experiences for potential users. It is also important to determine whether these features influence the content of the data collected. The purpose of this pilot study was to compare tablet computer and printed questionnaires as vehicles for the collection of psychosocial data from older adults to determine whether this digital platform would be readily adopted by the sample, and to identify whether mode effects are present. It was hypothesized that a significantly greater proportion of an older adult sample would prefer the tablet-delivered questionnaires, and it was also hypothesized that the collected data would not vary due to mode of delivery.

Methods

Design of Questionnaire and Inventory Evaluation via Tablets

The present study implemented a proprietary Web-based software package designed for the Apple iPad 2, with an interface that was customized for older adults (eg, large font sizes; high contrast between text, selected answer, and background; minimization of visual clutter) [9]. A battery composed of three questionnaires that include a wide range of answer types was selected to best capture differences in delivery media. The Barriers Self-Efficacy Scale (BARSE) [23] includes 13 Likert-type items, which ask the participants to rate their perceived ability to exercise at least three times per week in the face of various barriers. The Physical Activity Scale for the Elderly (PASE) [24] evaluates a number of leisure time sedentary and physical activity behaviors, and includes a number of conditional items. Finally, the Pittsburgh Sleep Quality Index (PSQI) [25] assesses quality of sleep and sleep disturbances. The PSQI also contains conditional items, as well as a number of short free-response items. For the purposes of the questionnaire and inventory evaluation via tablets (QUIET) study, these three questionnaires were provided in a

counterbalanced order to the participants in both print and digital formats.

The QuIET study software package was developed as a Web app with the use of hypertext markup language (HTML), cascading style sheets (CSS), JavaScript, and Perl programming languages. The package was designed aesthetically to resemble a pad of paper, and all navigation features were removed to simplify the interface. For short answer questions, participants used the iPad's digital keyboard to enter responses, and for Likert-type questions, participants were instructed to use a finger or stylus to touch their answer, which highlighted in response. Unlike printed questionnaire completion, for which users are able to gauge progress based on the number of pages completed or remaining, digital questionnaire completion offers no such physical indication of progress through the set. To account for this, a progress bar was included at the top of each page to indicate the portion of the total questionnaire battery completed, and a small motivational prompt indicating percent completion was provided between questionnaires. Though basic aesthetic elements were stylized to enhance clarity, the general layout and content of each questionnaire was the same in the print and digital versions. [Figure 1](#) shows a sample of a printed questionnaire.

To further enhance clarity, each questionnaire displayed only appropriate information when presenting conditional items. For example, when asking a question about the frequency with which participants engaged in walking behaviors, possible

choices included: (1) Never (Skip to next question), (2) Seldom (1-2 Days), (3) Sometimes (3-4 days), or (4) Often (5-7 days). While the question remained unanswered or if the participant chose "Never", the questionnaire only displayed the next question ([Figure 2](#) shows a screenshot of this display). Should one of the remaining three options be selected, a follow-up question was displayed asking about the number of hours per day spent doing the activity ([Figure 3](#) shows a screenshot of this display). This was intended to reduce confusion and errors associated with incorrectly answering conditional questions (eg, answering follow-up questions when not applicable).

To improve accuracy, user input was validated upon submission of each questionnaire. This validation was accomplished with JavaScript and Perl. In the case that a question was left unanswered, a prompt was given to the participant that alerted them to the specific question missed. They were given the option to answer the question or to skip it if they were unable to provide an answer. If a question was answered and a required follow-up question was skipped (eg, "How many hours did you do this activity?"), the user was alerted to the missed item and was unable to proceed until it had been answered. All numeric free-response items were also checked for plausibility. For instance, for an item inquiring about number of hours of sleep per night, if a participant entered a number greater than 24, they were prompted to revisit the question and edit their answer before being allowed to continue. After all data were validated, the participant was allowed to proceed to the next questionnaire.

Figure 1. Sample printed questionnaire.

PAGE_1/4

The following items are questions about your current level of physical activity and exercise. Please indicate your response by circling the appropriate number so we can assess your current level of physical activity. Select the response that most closely matches your own, remembering that there are no right or wrong answers.

LEISURE TIME ACTIVITY:

C1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV, or doing handicrafts?

1. NEVER (*SKIP TO C2*)
2. SELDOM (*1 - 2 DAYS*)
3. SOMETIMES (*3 - 4 DAYS*)
4. OFTEN (*5 - 7 DAYS*)

C1a. What were these activities?

C1b. On average, how many hours per day did you engage in these sitting activities?

1. LESS THAN 1 HOUR
2. 1 BUT LESS THAN 2 HOURS
3. 2 - 4 HOURS
4. MORE THAN 4 HOURS

C2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

1. NEVER (*SKIP TO C3*)
2. SELDOM (*1 - 2 DAYS*)
3. SOMETIMES (*3 - 4 DAYS*)
4. OFTEN (*5 - 7 DAYS*)

C2a. On average, how many hours per day did you spend walking?

1. LESS THAN 1 HOUR
2. 1 BUT LESS THAN 2 HOURS
3. 2 - 4 HOURS
4. MORE THAN 4 HOURS

Figure 2. Sample questionnaire without follow-up items.

iPad 9:13 AM 68%

PASE

1. NEVER (Continue to Question 2)

2. SELDOM (1 - 2 DAYS)

3. SOMETIMES (3 - 4 DAYS)

4. OFTEN (5 - 7 DAYS)

Question 2: Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

1. NEVER (Continue to Question 3)

2. SELDOM (1 - 2 DAYS)

3. SOMETIMES (3 - 4 DAYS)

4. OFTEN (5 - 7 DAYS)

Question 3: Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier, or other similar activities?

1. NEVER (Continue to Question 4)

2. SELDOM (1 - 2 DAYS)

3. SOMETIMES (3 - 4 DAYS)

4. OFTEN (5 - 7 DAYS)

Figure 3. Sample questionnaire with follow-up items.

iPad 9:13 AM 68%

PASE

1. NEVER (Continue to Question 2)

2. SELDOM (1 - 2 DAYS)

3. SOMETIMES (3 - 4 DAYS)

4. OFTEN (5 - 7 DAYS)

Question 2: Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

1. NEVER (Continue to Question 3)

2. SELDOM (1 - 2 DAYS)

3. SOMETIMES (3 - 4 DAYS)

4. OFTEN (5 - 7 DAYS)

Q2a. On average, how many hours per day did you spend walking?

1. LESS THAN 1 HOUR

2. 1 BUT LESS THAN 2 HOURS

3. 2 - 4 HOURS

4. MORE THAN 4 HOURS

Question 3: Over the past 7 days, how often did you engage in

Recruitment, Screening, and Randomization

Due to the nature of the primary research question (ie, will a significantly greater proportion of a sample of older adults prefer digitally delivered questionnaires), an estimated minimum of 38 participants was needed to detect whether 75% of participants preferring the digital questionnaire was significantly different from 50% preferring each method. This estimate was calculated at a 5% level of significance, 80% power (two-sided test), and with a dropout rate of 25%.

A number of methods were used to recruit community dwelling older adults. Short recruitment talks were given to local older adult philanthropy groups, life-long learning program participants, and senior exercise group participants. Additionally, emails were sent to individuals in existing study databases that agreed to participate in future research. Eligible individuals were English speaking, free from cognitive impairment as assessed via the Modified Telephone Interview for Cognitive Status [26], and willing to attend a single session at the research center.

Depending on individual preference, participant screening was conducted on the Internet or by telephone. During the initial screening process, demographics as well as information pertaining to current computer and mobile device use habits were collected. This included the type of mobile devices used (ie, smartphone, tablet, e-reader), number of hours the computer and mobile devices were typically used, and the reason for using these devices. After this screening process, participants registered for a one hour appointment at the research center. Upon recruitment closure, participants were randomly assigned to one of two groups: (1) the iPad-first group that received the tablet-based questionnaires prior to receiving the paper-based questionnaire packet, or (2) the paper-first group that received the printed questionnaires first. Due to the small number of questionnaires provided, participants received and completed their second set of questionnaires upon completion of the first.

Measurement and Evaluation

At the end of the testing session, an evaluation of the process of questionnaire completion was given to each participant. Using a four point scale, participants were asked to rate ease of use, as well as their perceived level of arousal for each delivery type. They were asked to comment on strengths, weaknesses, and features to change for each medium. Finally, they were asked to indicate which method they preferred. All data were compiled and analyzed using SPSS version 21 for Windows [27]. Study protocols were reviewed and approved by a university Institutional Review Board, and all participants signed an informed consent document.

Results

Participants

A total of 56 individuals responded to recruitment efforts. There were two individuals that were too young to participate, one

was unable to attend a session at the study center, and four qualified to participate, but did not attend their scheduled session. The participants who completed the study ($N=49$; median age 64; interquartile range [IQR]=57-71) were mostly female (36/49, 74%), caucasian (39/49, 80%), and well educated (21/49, 43% with a graduate degree; see Table 1). Greater than half of the study participants used a mobile device daily ($n=25$), 94% used a computer daily ($n=46$), 13 owned a smartphone, and 18 owned a tablet computer or e-reader (see Table 2).

Preferred Method of Questionnaire Delivery

A nonparametric one-sample binomial test indicated a significantly greater proportion of individuals preferred the tablet-delivered questionnaires to the traditional pen and paper method ($z=4.96$, SE 3.428, $P<.001$). Normally distributed scale scores were compared using paired-sample t tests, and Wilcoxon sign-rank tests were used to compare scale scores that were not normally distributed. These tests indicated that measures collected by each method were not significantly different (all $P\geq.273$; see Tables 3 and 4).

The association between preferred delivery method and daily mobile device use approached significance ($r_s=.28$, $n=47$, $P=.06$), and the association between preferred delivery method and daily computer use was significant ($r_s=.42$, $n=47$, $P<.05$), such that those who preferred paper delivery were less likely to use a mobile device or computer each day. The perceived ease of use of the tablet interface, as well as reported anxiety while completing the digital questionnaires, were also significantly correlated with preferences ($r_s=.665$, $n=47$, $P<.001$ and $r_s=.552$, $n=47$, $P<.001$, respectively), indicating that those who preferred the digital delivery method were more likely to find it easier to use and were less anxious while using it. Preferred delivery method was not significantly correlated with the remaining device-use variables (ie, number of hours of daily computer use, type of mobile device owned, hours of mobile device use), perceived ease of use of the paper packet, or reported anxiety felt while completing printed questionnaires.

With regard to strengths of the tablet delivery, participants most frequently noted improved speed of use ($n = 16$; eg, "Was quicker than writing. Didn't get messy") and ease of entry ($n = 8$; eg, "Very easy to choose answers"). The most commonly cited weaknesses were related to navigation ($n=5$; eg, "I had trouble getting used to scrolling") and formatting ($n=5$; eg, "Difficulty with time [input] box").

Regarding paper delivery, commonly noted strengths related to readability ($n=14$; eg, "Can see everything at the same time") and navigation ($n=7$; eg, "Can skip ahead, look back"). The participants most commonly stated that the paper packet was time consuming or cumbersome ($n=8$; eg, "Seemed more time consuming and longer") and was not dynamic ($n=6$; eg, "Not clear that you could skip questions if you hadn't answered initial question").

Table 1. Sample demographics.

Variable	PF ^a , n	IF ^b , n	χ^2	Total, N=49	df ^c	P
Sex			.004	49	1	.947
Male	7	6				
Female	19	17				
Race			0.3	42	1	.607
Caucasian	19	20				
African American	1	2				
Not reported	6	1				
Ethnicity			0.9	42	1	.335
Hispanic or Latino	0	1				
Not Hispanic or Latino	20	21				
Not reported	6	1				
Education			2.4	42	1	.448
<High school graduate	1	0				
High school graduate	0	1				
College or vocational school degree	8	11				
Graduate level degree	11	10				
Not reported	6	1				
Income			3.9	42	6	.701
< US \$40,000 per year	4	4				
> US \$40,000 per year	9	14				
Prefer not to answer	7	4				
Not reported	6	1				

^aPF=Paper-first group^bIF=iPad-first group^cdf=degrees of freedom

Table 2. Sample device use.

Variable	PF ^a , n	IF ^b , n	χ^2	Total, N=49	df ^c	P
Use computer daily			0.2	49	1	.626
Yes	24	22				
No	2	1				
Use mobile device daily			3.5	49	1	.062
Yes	10	15				
No	16	8				
Use smartphone			0.3	49	1	.560
Yes	6	7				
No	20	16				
Use tablet or e-reader			0.8	49	1	.357
Yes	8	10				
No	18	13				

^aPF=Paper-first group^bIF=iPad-first group^cdf=degrees of freedom**Table 3.** Scale scores for digital and print questionnaires.

Scale score	Digital, mean (SD)	Print, mean (SD)	N	95% CI ^a for mean difference	<i>t</i> ^c	df ^b	P
PASE total score	139.43 (68.50)	140.50 (68.33)	49	-7.15, 5.00	-0.356	48	.724
BARSE total score	58.95 (25.04)	59.18 (24.56)	49	-1.66, 1.19	-0.332	48	.741

^aCI=confidence interval^bdf=degrees of freedom^cStudent's *t* test**Table 4.** Scale scores for digital and print questionnaires.

Scale score	Digital, median (IQR)	Print, median (IQR)	N	<i>z</i> ^a	P
PSQI global score	6.00(3.00-8.00)	5.00(2.00-8.00)	49	1.096	.273

^aWilcoxon sign-rank test

Discussion

Principal Findings

This study provides preliminary evidence in support of the use of contemporary tablet computer devices for collecting psychosocial questionnaire data. The results indicated that a significant majority of older adult participants preferred tablet delivery of the questionnaires. Participants did not respond differently to questionnaire items based on the method of delivery, a finding that is in line with previous research [4]. Surprisingly, despite relatively few individuals owning tablet computers or e-readers, study participants frequently indicated that they felt the tablet-based questionnaire battery was faster and easier to use than the paper packet.

Importantly, findings from this pilot study indicate that older adults may respond positively to and indeed prefer completing digital questionnaires on tablet devices equipped with software like the package designed for this study. Such dynamic and

interactive user environments might benefit participants tasked with completing lengthy questionnaire batteries. For example, hiding unneeded follow-up questions on conditional items resulted in a questionnaire that appeared shorter, a finding reflected in user testimonials. Customized and informative prompts can provide motivation and information between questionnaires [5], and the removal of input devices (eg, keyboard and mouse) creates an environment where entry is more natural and intuitive, even for those less familiar with computer technology [8]. Finally, because data are validated as they are entered, participants are able to explicitly and privately state whether they intended to leave a question unanswered, allowing them to avoid being approached to answer potentially sensitive items.

Researchers also benefit from such computerized methods of data collection. Digital data collection removes the need for research staff to manually enter data, and real time validation ensures that collected data are accurate. Although Web-based data collection conducted via PC can take advantage of some

of these same features, the interactive nature of touchscreen devices and the ability to create a simple, clutter-free interface allow researchers to deliver a user experience that is likely more comfortable for many older adults. Finally, because Web apps are cross-platform compatible, and because older adults are increasingly purchasing tablet computers, the ability to deliver questionnaires in a digital format may make it easier for researchers to collect data from broader and more diverse populations.

Strengths

We believe that this study possesses several strengths. It provides preliminary evidence that with the use of a population-specific interface, older adults may find tablet computer-delivered questionnaires to be acceptable, and perhaps preferable to traditional printed methods. Additionally, this study successfully implemented a tablet-based Web app to collect psychosocial questionnaire data. In the context of questionnaire delivery, we believe that the use of a Web app provides several important advantages to the researcher. First, it can be readily designed to be cross-platform compatible, allowing owners of a variety of tablet computer platforms to access study materials. Further, because Web apps do not require that users install software on their device, researchers need only provide study participants a hyperlink to access questionnaires. This may allow researchers to recruit from a broader geographic area without requiring that participants visit the research center.

This study also provides early evidence to suggest that data collected via tablet computer do not statistically differ from those collected with printed questionnaires. Due to the unique characteristics of the platform, this finding is an important first step in establishing the utility of the device in the research context.

Limitations and Future Directions

It is important, however, to recognize the limitations of this study. First, the sample was primarily female (36/49, 74%). There are, however, proportionately more women than men in the older adult population, and this gender makeup is similar to that seen in many health-related randomized controlled trials [28,29]. The sample recruited for this study also tended to be well educated, and a large proportion (46/49, 94%) used a

computer on a daily basis. Accordingly, these individuals may be relatively tech-savvy in comparison with the general population of older adults in the United States, of which roughly half report using the Internet [30]. This may limit the generalizability of the findings, as well as our ability to draw definitive conclusions. Further research targeting lower income and less educated individuals is warranted, as these groups are the least likely to use computer or Internet technologies [31,32]. Additionally, relative to those who did not use a mobile device each day, those who used a mobile device daily appear to be more likely to prefer the tablet-based delivery method. It has been suggested that older adults' self-efficacy for engaging with and learning about new technology develops in response to previous experiences (eg, in the workplace) and to the environment [6]. It may be beneficial to extend this work further by examining how psychosocial factors, such as self-efficacy, as well as physical factors such as visual or memory impairment, may influence these preferences.

Regarding program design, the decision to require individuals to complete any question should not be taken lightly, as individuals may have valid reasons to leave a question unanswered. In the context of the current study, only questions which provided clarification for an initial question (eg, the number of hours spent in an activity) were required in order to avoid such conflicts, while all other items allowed participants to explicitly state their intent to leave the item unanswered. Finally, it is possible that the progress bar and short motivational messages could bias participant responses. Follow-up research may benefit by providing questionnaires with and without these features to examine whether differences are present.

Conclusions

The findings from this pilot study indicate that psychosocial questionnaires, when designed for older adults and delivered via touchscreen enabled tablet computers, may improve efficiency of data collection and may provide more accurate data for the researcher. Importantly, tablet computer-based questionnaire delivery does not appear to influence the content of the data collected. With the aid of additional research, these digitally delivered questionnaires may prove beneficial to the study of HRQL in older adults.

Conflicts of Interest

None declared.

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Abbreviations

BARSE: Barriers Self-Efficacy Scale
HRQL: health-related quality of life
IQR: interquartile range
PASE: Physical Activity Scale for the Elderly
PC: personal computer
PSQI: Pittsburgh Sleep Quality Index
QuIET: questionnaire and inventory evaluation via tablets

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Original Paper

The Comparability of Men Who Have Sex With Men Recruited From Venue-Time-Space Sampling and Facebook: A Cohort Study

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Abstract

Background: Recruiting valid samples of men who have sex with men (MSM) is a key component of the US human immunodeficiency virus (HIV) surveillance and of research studies seeking to improve HIV prevention for MSM. Social media, such as Facebook, may present an opportunity to reach broad samples of MSM, but the extent to which those samples are comparable with men recruited from venue-based, time-space sampling (VBTS) is unknown.

Objective: The objective of this study was to assess the comparability of MSM recruited via VBTS and Facebook.

Methods: HIV-negative and HIV-positive black and white MSM were recruited from June 2010 to December 2012 using VBTS and Facebook in Atlanta, GA. We compared the self-reported venue attendance, demographic characteristics, sexual and risk behaviors, history of HIV-testing, and HIV and sexually transmitted infection (STI) prevalence between Facebook- and VBTS-recruited MSM overall and by race. Multivariate logistic and negative binomial models estimated age/race adjusted ratios. The Kaplan-Meier method was used to assess 24-month retention.

Results: We recruited 803 MSM, of whom 110 (34/110, 30.9% black MSM, 76/110, 69.1% white MSM) were recruited via Facebook and 693 (420/693, 60.6% black MSM, 273/693, 39.4% white MSM) were recruited through VBTS. Facebook recruits had high rates of venue attendance in the previous month (26/34, 77% among black and 71/76, 93% among white MSM; between-race $P=.01$). MSM recruited on Facebook were generally older, with significant age differences among black MSM ($P=.02$), but not white MSM ($P=.14$). In adjusted multivariate models, VBTS-recruited MSM had fewer total partners (risk ratio [RR]=0.78, 95% CI 0.64-0.95; $P=.01$) and unprotected anal intercourse (UAI) partners (RR=0.54, 95% CI 0.40-0.72; $P<.001$) in the previous 12 months. No significant differences were observed in HIV testing or HIV/STI prevalence. Retention to the 24-month visit varied from 81% for black and 70% for white MSM recruited via Facebook, to 77% for black and 78% for white MSM recruited at venues. There was no statistically significant differences in retention between the four groups (log-rank $P=.64$).

Conclusions: VBTS and Facebook recruitment methods yielded similar samples of MSM in terms of HIV-testing patterns, and prevalence of HIV/STI, with no differences in study retention. Most Facebook-recruited men also attended venues where VBTS

recruitment was conducted. Surveillance and research studies may recruit via Facebook with little evidence of bias, relative to VBTS.

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KEYWORDS

men who have sex with men, MSM; Facebook; venue-based time sampling; online MSM; social media recruitment of MSM

Introduction

In the United States, men who have sex with men (MSM) are disproportionately affected by human immunodeficiency virus infection/acquired immunodeficiency syndrome (HIV/AIDS). At the end of 2009, MSM represented 52% of all people in the United States living with HIV, and are the only population for which new infections continue to increase [1]. Increases in HIV incidence are especially high among young MSM and MSM of color [2]. Recruiting valid samples of MSM is a key component of US HIV behavioral and clinical surveillance, and of research studies that seek to improve HIV prevention for MSM.

The National HIV Behavioral Surveillance System (NHBS) [3] and research studies [4-7] have relied, in part, on venue-based, time-space sampling (VBTS) [8] for the recruitment of MSM populations. In VBTS, after a period of formative research, venues (eg, bars, dance-clubs) attended by MSM are identified by health department staff members and calendars marking the days and times of venue attendance are created. Afterwards, venues, days, and times are randomly chosen for recruitment each month [8]. Although it is an effective method to recruit MSM and to minimize some types of biases, it has limitations. First, hiring, training, and retaining outreach staff is difficult as recruitment at venues requires staff that (1) are able to work highly variable schedules, including late nights and weekends, in outdoor settings, and poor weather, (2) collect valid and reliable data in many different venues, (3) minimize adverse events in venues, such as encounters with intoxicated and disorderly patrons, and (4) be culturally competent and racially diverse. Second, venues must be relatively safe for staff, a minimum of 2 staff members must be present during recruitment, and venue-owner approval of date/time block selected for recruitment is required, making VBTS logistically challenging. Third, support from the MSM community (eg, members of HIV prevention community planning groups, MSM community-based organizations, and advocacy groups) is crucial to formative research and the identification and access to important venues. Finally, seasonal patterns of venue attendance are an important barrier to recruitment [8]. Additionally, there are still concerns about how to best control for selection bias in VBTS due to the unequal sampling probabilities of participants, because MSM who visit gay venues more frequently are more likely to be sampled [8-11]. The limitations of VBTS, have led to an interest in developing other sampling methods that may allow researchers to complement VBTS by reaching comparable populations; the Internet and social media may present such an opportunity.

The growth of the Internet, social networking websites, and mobile technology usage, especially among minorities, have presented new opportunities for recruiting and studying MSM

populations. In 2013, approximately 85% of adults living in the United States used the Internet [12], 71% of men aged 18 years of age or older were Facebook users, and 84% of all Internet users aged 18 to 29 had a Facebook account [13]. In a 2012 Pew survey, social media usage was higher among Hispanics (72%) and non-Hispanic blacks (68%) than among non-Hispanic whites (65%) [13]. Although there are few accurate estimates of Internet and social media usage by MSM, a meta-analysis by Liau et al [14] showed that 40% of MSM sought partners online. A more recent study among MSM social media users reported that 67% of study participants used social media to meet partners [15].

Online recruitment presents potential advantages over VBTS: it has a greater reach, is less time consuming, and less expensive [16,17]. However, online recruitment methods are not without limitations; Internet research has relied on convenience samples, and determining the source population limits the external validity of results [18]. A recent study identified that banner-advertisement recruitment methods may underrepresent minority MSM, MSM with less education, and MSM who do not identify as gay [19]. Finally, excluding duplicate responders and computer robots, which can perform a wide variety of automated tasks on the Internet, determining adequate compensation, ensuring confidentiality, and developing appropriate consent procedures continue to be important concerns [20].

The comparability of online and VBTS samples of MSM has recently received scrutiny, with the former method generally considered to yield higher risk samples [14,21-24]. To date, most Web-based studies of MSM have been cross-sectional with sampling occurring at specific online venues that are believed to contain higher-risk individuals (eg, Craigslist, Manhunt, Grindr), have had low minority representation, and used self-reported data on HIV or sexually transmitted infections (STI) [24-27]. Facebook is a social networking site where a wide range of social interactions occur and, in comparison with other online venues, is not specifically used for seeking sex partners. No studies to date have addressed the comparability of MSM recruited via VBTS and Facebook regarding venue attendance patterns, sexual and risk behaviors, and biological data about HIV and STIs. Finally, although the ability to recruit and retain a Web-based follow-up study using email and text messaging has been demonstrated [28,29], the relative success of retention in MSM in in-person studies recruited using online and VBTS methods is untested.

We performed a secondary analysis of Atlanta MSM recruited through VBTS and Facebook who enrolled in a longitudinal HIV prevention study with the objective of determining the comparability of samples of MSM recruited through VBTS and Facebook. To meet this objective we compared the recent venue

and online site attendance, baseline behaviors, prevalent HIV/STI, and study retention by recruitment method. This analysis addressed a number of gaps; first, Web-based recruitment of MSM for an “in person” study has not been reported from Atlanta [17,25,30]; second, we enrolled a balanced sample of black and white MSM; third, we obtained laboratory-confirmed outcomes for HIV and STIs; and finally, the longitudinal nature of our study allowed us to quantify retention by mode of recruitment.

Methods

Recruitment and Enrollment

InvolveMENT (MEN is capitalized to highlight MSM) was a prospective cohort at Emory University designed to study the individual, dyadic, and community level factors that may contribute to the disparities in HIV and STI prevalence and incidence between black and white MSM in Atlanta, Georgia. The study methods have been described [31]. Briefly, approximately equal numbers of HIV-negative and HIV-positive black and white MSM were recruited from June 2010 to December 2012 using VBTS. Recognizing the growing importance of Facebook as a social space for MSM and to increase recruitment, Facebook was included as a venue within our sampling frame 6 months after enrollment began. Facebook encompasses a broad range of social interactions that aligned with the variety of venues sampled through VBTS (eg, bars, clubs, coffee shops, restaurants). Recruitment through Facebook took place from January 2011 to December 2012 via placement of banner advertisements.

The VBTS approach used was based on NHBS [8,32], and the initial venue sample frame was adopted from that used in Atlanta for the 2008 MSM cycle of the NHBS. Types of venues included in the sampling frame included bars, dance clubs, fitness clubs or gymnasiums, Gay Pride events, parks, restaurants, retail businesses, sex establishments, social organizations, street locations, and other special events. Venue-date-time units were randomly sampled. At sampled venue-day-time units, male attendees were systematically sampled and approached by the study staff and administered a recruitment script and screening questions using a hand-held device. For Facebook sampling, paid banner advertisements were placed in the Facebook advertising interface. Advertisements were delivered only to men 18 years of age or older who selected residing in Atlanta and interest in relationships with other men as demographic options on their Facebook profiles. Participants clicking on the banner advertisements were redirected to a Web-based survey where, after giving consent to screening, they were administered the same screening questions used for VBTS recruitment.

At the enrollment visit, potential participants were screened again for eligibility. Following the written informed consent process, participants were tested for HIV, chlamydia and gonorrhea (urethral and rectal), syphilis, and substances of abuse (urine dipstick) [31]. Participants completed a baseline computer-administered self-interview questionnaire. Those who tested HIV-negative were prospectively followed for 2 years, with visits at 3, 6, 9, 12, 18, and 24 months. This study was

approved by the Emory University institutional review board (protocol 42405).

Questionnaire Measures

The questionnaire used in InvolveMENT is published [31]; responses to the baseline questionnaire were used in the present analysis. To assess recent social media usage and Atlanta venue attendance, participants were asked the following: (1) Which of the following websites have you visited in the last month? (select all that apply): MySpace, Craigslist, Manhunt, FindFred, Black Gay Chat/BCGLive.com, Facebook, Adam4Adam, D-list, Friendster and OKCupid, (2) In the last month, in Atlanta, have you visited?: a) Bars/restaurants such as (8 local MSM-frequented bars/restaurants); b) Gyms such as (4 local MSM-frequented gyms); c) Clubs such as (3 local MSM-frequented clubs); d) Social gatherings such as (3 local MSM social groups); e) Outdoor locations such as (2 local MSM-frequented outdoor locations); or f) Bath houses such as (3 local MSM-frequented bath houses).

Sexual risk behaviors were collected as partner totals. Alcohol abuse was assessed using the CAGE scale (CAGE is an acronym of the 4 questions used in the scale [“Cut,” “Annoyed,” “Guilty,” “Eye-opener”]), a validated method used to measure alcohol dependence [33]. Using partnership-level responses on up to 5 most recent sex partners in 6 months, we created additional individual-level measures of partners met online, any serodiscussion [34], any sex with a discordant (ie, when one partner is infected but not the other) or unknown status partner, and alcohol or drug use at last sex.

Analytical Methods

InvolveMENT used race-stratified sampling to ensure that equal numbers of black and white MSM were recruited, thus, to adhere to the design of our study and to understand race-specific aspects of recruitment all results were examined stratified by race. Participant use of social media and visits to Atlanta venues in the previous month was summarized and compared by recruitment method (VBTS and Facebook) using the Pearson chi-square test. For individuals recruited via VBTS, differences in Facebook use overall and by venue of recruitment were described.

Demographic characteristics were described for both recruitment methods overall and by race; differences were compared using Pearson chi-square tests. The age eligibility of participants was capped at 40 before Facebook recruitment began; participants 40 or older recruited through VBTS were excluded from the analysis (n=25). Partner counts were described as medians and group differences were tested using Wald chi-square tests in bivariate negative-binomial regression. Substance use, partnership attributes, HIV testing history, and prevalence of HIV/STI were summarized as proportions and tested using Pearson chi-square tests. The prevalence of urethral STI in our sample was too small to permit analysis. In comparisons where an expected cell count had <5 observations, Fisher’s exact test was used. To assess whether the within-race differences by recruitment methods differed among black and white MSM interactions of age, education, and partner counts with race were tested using likelihood ratio (LR) tests in logistic and negative

binomial regression, respectively, and the Breslow-Day test was used to test interactions between race and employment, poverty, substance use, partnership attributes, HIV-testing history, and HIV/STI prevalence.

Due to significant differences in the age distribution between recruitment methods, we used multivariate models to assess whether levels of key outcomes differed when controlling for race and age. We used multiple multivariate logistic regression models to estimate the effect of recruitment for dichotomous outcomes, with comparisons made using predicted marginal prevalence ratios (PR) and Wald chi-square tests. For partner counts, outcomes were modeled using negative binomial regression, although Poisson and log-linear models were also considered. All models yielded similar parameter estimates and *P* values, and a goodness of fit test that compared the negative binomial and Poisson models [35] found that the negative binomial provided the best fit. Measures of association estimated in negative binomial models were risk ratios (RRs). All logistic and negative binomial models included race, age, and recruitment-method terms. Due to a borderline nonsignificant (*P*=.056) difference in HIV-positive proportions between Facebook and Atlanta-venue recruits among white MSM, baseline-HIV status was included in models of partner counts. An interaction term between recruitment method and race was included when modeling the outcome of syphilis infection because we detected a significant interaction using the Breslow-Day test, and was tested with a likelihood ratio test during our modeling procedure.

Retention to the 24-month visit was analyzed using the Kaplan-Meier method. Log-rank tests were performed to compare recruitment groups by race. All associations were considered significant at the α =.05 level. All analyses were performed using SAS V9.3.

Results

Recruitment and Costs

Screening for Involvement occurred from July 2010 through December 2012 with sampling occurring at 605 events located at 94 individual venues. Of 19,931 men approached at Atlanta venues, 45.07% (8,983/19,931) were screened, and 10.76% (2,144/19,931) were eligible on initial screening. Of 6,092 men who clicked on the Facebook advertisement, 22.32% (1,360/6,092) were screened, and 3.02% (184/6,092) were eligible on initial screening. The Facebook to VBTS cost per

enrollee ratio was 0.75; the estimated costs of recruitment are available in [Multimedia Appendix 1](#).

Sample Characteristics and Venue Attendance

A total of 803 MSM were included in the analysis, of whom 13.7% (110/803) were recruited via Facebook and 86.3% (693/803) were recruited at Atlanta venues. Of Facebook recruits, 30.9% (34/110) were black MSM and 69.1% (76/110) were white MSM; overall 7.5% (34/453) of black MSM and 21.8% (76/349) of white MSM were recruited via Facebook. Among MSM recruited at Atlanta venues, 60.6% (420/693) were black and 39.4% (273/693) were white. Internet use and Atlanta venue attendance in the previous month are shown in [Table 1](#). Among MSM recruited at Atlanta venues, 61.9% (260/420) of black and 58.2% (159/273) of white MSM had used Facebook in the previous month (between-race *P*=.31), and Facebook recruits were more likely to have used other forms of social media (eg, Craigslist, Manhunt, Adam4Adam) compared with Atlanta venue recruits. Among MSM recruited through Facebook, 77% (26/34) black MSM and 93% (68/76) white MSM had visited an Atlanta venue in the previous month (between-race *P*=.01). Facebook use differed by venue recruitment site ranging from 41% (24/58) for those recruited at street locations to 79% (38/48) for those recruited at cafes and restaurants (*P*<.001; data not shown).

Demographic Characteristics, HIV Risk and Prevention Behaviors, and HIV/STI Prevalence

Demographic comparisons by recruitment method are shown in [Table 2](#). MSM recruited on Facebook were generally older, with significant age differences among black MSM (*P*=.02), but not white MSM. White MSM recruited at Atlanta venues had a higher education level than their Facebook counterparts (*P*=.01), with no difference among black MSM. Conversely, MSM recruited at Atlanta venues were more likely to report current employment compared with Facebook recruits (*P*=.047), with significant differences among black MSM (*P*=.04) but not white MSM (*P*=.05). Interactions between race and demographic variables were not significant.

The number of total and UAI partners in the previous 12 months were higher for Facebook recruits compared with Atlanta-venue recruits overall and among white MSM ([Table 3](#)). Facebook recruits were more likely to report having met at least 1 partner online (*P*=.006). Tests of interaction between race and recruitment type for risk behavior outcomes, substance use, partnership attributes, and HIV-testing were all non-significant.

Table 1. Internet use and real-world venue attendance in the previous month by recruitment type (Facebook vs Atlanta Venues) and race, InvolveMENT, Atlanta, GA.

	Total			Black			White			<i>P</i>
	Facebook (n=110) n (%)	Atlanta venue (n=693)	<i>P</i>	Facebook (n=34) n (%)	Atlanta venue (n=420)	<i>P</i>	Facebook (n=76) n (%)	Atlanta venue (n=273)	<i>P</i>	
Internet use										
Used Facebook	110/110 (100.0)	419/692 (60.5)	-	34/34 (100.0)	260/419 (62.1)	-	76/76 (100.0)	159/273 (58.2)	-	
Visited at least one Internet site in the past month ^a	96/110 (87.3)	332/693 (47.9)	<.001	28/34 (82.4)	216/420 (51.4)	<.001	68/76 (89.5)	116/273 (42.5)	<.001	
Real-world										
Attended at least 1 venue in the past month ^b	97/110 (88.2)	436/448 (97.3)	<.001	26/34 (76.5)	273/283 (96.5)	<.001	71/76 (93.4)	163/165 (98.8)	.03	

^aDoes not include Facebook.

^bTotal offline venue attendance does not add up to 100% because venue-based, time-space sampling (VBTS) also sampled at street locations and during Gay Pride, thus all VBTS recruits did not necessarily visit one of the venues in the previous month.

Table 2. Demographic characteristics by recruitment type (Facebook vs Atlanta Venues) and race InvolveMENT, Atlanta, GA.

Demographics	Total			Black			White			Race Interaction	
	Facebook (n=110) n (%)	Atlanta venue (n=693)	<i>P</i>	Facebook (n=34) n (%)	Atlanta venue (n=420)	<i>P</i>	Facebook (n=76) n (%)	Atlanta venue (n=273)	<i>P</i>	<i>P</i>	
Age category	n=110	n=693	.03	n=34	n=420	.02	n=76	n=273	.14	.69	
18-19	11/110 (10.0)	32/668 (4.8)		5/34 (14.7)	22/411 (5.4)		6/76 (7.9)	10/257 (3.9)			
20-24	24/110 (21.8)	223/668 (33.4)		5/34 (14.7)	51/411 (36.7)		19/76 (25.0)	72/257 (28.0)			
25-29	35/110 (31.8)	204/668 (30.5)		14/34 (41.2)	123/411 (29.9)		24/76 (31.6)	81/257 (31.5)			
30-39	34/110 (30.9)	209/668 (31.3)		10/34 (29.4)	115/411 (28.0)		27/76 (35.5)	94/257 (36.6)			
40+ ^a	N/A	n=25		N/A	n=9		N/A	n=16			
Education	n=110	n=689	.10	n=34	n=417	.11	n=76	n=272	.01	.45	
<High school	2/110 (1.8)	16/689 (2.3)		2/34 (6.0)	14/417 (3.4)		0/76 (0.0)	2/272 (0.7)			
High school /general educated development	22/110 (20.0)	111/689 (16.1)		10/34 (29.4)	89/417 (21.3)		12/76 (15.8)	22/272 (8.1)			
Some college	53/110 (48.2)	272/689 (39.5)		18/34 (52.9)	183/417 (43.9)		35/76 (46.1)	89/272 (32.7)			
College or >	33/110 (30.0)	290/689 (42.1)		4/34 (11.8)	131/417 (31.4)		29/76 (38.2)	159/272 (58.5)			
Employed	72/107 (67.3)	526/690 (76.2)	.047	17/31 (54.8)	301/417 (72.2)	.04	55/76 (72.4)	225/273 (82.4)	.05	.71	
Poverty	19/95 (20.0)	119/593 (20.1)	.99	9/25 (36.0)	88/342 (25.7)	.26	10/70 (14.3)	31/251 (12.4)	.67	.59	

^aEnrollment through Facebook took place after the maximum recruitment age was capped at 40, thus no percentages are presented for this category.

Table 3. HIV risk and prevention behaviors by recruitment type (Facebook vs Atlanta Venues) and race, InvolveMENT, Atlanta, GA.

	Total			Black			White			Race Inter-action	
	Facebook	Atlanta venue	<i>P</i>	Facebook	Atlanta venue	<i>P</i>	Facebook	Atlanta venue	<i>P</i>	<i>P</i>	
	(n=110)	(n=693)		(n=34)	(n=420)		(n=76)	(n=273)			
	Median (IQR)			Median (IQR)			Median (IQR)				
Risk behaviors a,b											
Total # male partners	8 (4-15)	6 (3-10)	.002	5 (3-9)	5 (3-10)	.92	9 (5-20)	7 (4-12)	.005	.45	
Main male partners	1 (0-2)	1 (0-2)	.98	1 (0 - 2)	1 (1-2)	.34	1 (0-2)	1 (0-2)	.06	.45	
Casual male partners	5.5 (3-12)	4 (2-10)	.03	4 (2 - 8)	4 (2-8)	.88	7 (3-18)	6 (3-11)	.06	.23	
UAI partners	2 (1-5)	1 (0-3)	<.001	2 (1 – 3.5)	1 (0-3)	.16	2 (1-5)	1 (1-3)	<.001	.17	
Substance use, n (%)											
Alcohol dependence	21/110 (19.1)	204/693 (29.3)	.03	4/34 (11.8)	93/420 (22.1)	.16	17/76 (22.3)	111/273 (40.7)	.003	.86	
Marijuana ^c	26/110 (23.6)	162/693 (23.4)	.95	9/34 (26.5)	112/420 (26.7)	.98	17/76 (22.3)	50/273 (18.3)	.43	.61	
Cocaine ^c	4/110 (3.6)	51/693 (7.4)	.15	2/34 (5.9)	34/420 (8.1)	1	2/76 (2.6)	17/273 (6.3)	.39	.6	
Other noninjection drugs ^c	8/110 (7.3)	14/693 (2.0)	.006	2/34 (5.9)	8/420 (1.9)	.17	6/76 (7.9)	6/273 (2.2)	.03	.87	
Partnership attributes, n (%)											
Met at least 1 partner online	79/110 (71.8)	402/693 (58.0)	.006	22/34 (64.7)	234/420 (55.7)	.31	57/76 (75.0)	168/273 (61.5)	.03	.59	
Discussed serostatus with at least 1 partner	94/110 (85.5)	551/693 (79.5)	.14	26/34 (76.5)	310/420 (73.8)	.73	241/273 (88.3)	68/76 (89.5)	.77	.97	
Any discordant partner	78/110 (70.9)	482/693 (69.6)	.77	26/34 (76.5)	314/420 (74.8)	.83	52/76 (68.4)	168/273 (61.5)	.27	.68	
Used alcohol or drugs at last sex	33/110 (30.0)	209/693 (30.2)	.95	110/420 (26.2)	9/34 (26.5)	.97	24/76 (31.6)	96/273 (35.2)	.56	.72	
HIV-testing history, n (%)											
Lifetime	100/110 (90.9)	648/691 (93.7)	.26	31/34 (91.2)	386/418 (92.3)	.74	69/76 (90.8)	262/331 (79.2)	.07	.82	
Lifetime ^d	74/84 (88.1)	508/551 (92.2)	.21	20/23 (87.0)	269/301 (89.4)	.73	54/61 (88.5)	239/250 (95.6)	.06	.32	
Previous 12 months ^d	59/84 (70.2)	384/550 (69.8)	.94	17/23 (73.9)	197/300 (66.7)	.42	42/61 (68.9)	187/250 (74.8)	.35	.23	

^aPartners in the previous 12 months.

^bExtreme values capped at the following values: a) 125 total partners in the previous 12 months; b) 25 main male partners in the previous 12 months; c) 100 casual partners in the previous 12 months; and d) 125 UAI partners in the previous 12 months.

^cUrine-detected.

^dExcluding HIV+ aware.

HIV and STI prevalence at baseline is presented in Table 4. HIV test results at baseline were similar for MSM recruited via Facebook and Atlanta venues within each racial group. Although within-race differences between Facebook and Atlanta-venue recruits were nonsignificant, Atlanta-venue recruits overall were more likely to be infected with a rectal STI compared with Facebook recruits. The significant interaction between race and

recruitment method ($P=.03$) for syphilis indicates that while within-race differences between Atlanta-venue and Facebook recruits were not significant, there were significant differences between black and white MSM recruited via Facebook as well as black and white MSM recruited at Atlanta venues.

Multivariate models adjusting simultaneously for race and age are presented in Table 5, and were similar to results obtained

in bivariate analyses. Atlanta-venue recruits had fewer total partners (RR=0.79, 95% CI 0.65-0.95) and UAI partners (RR=0.56, 95% CI 0.42-0.73) in the previous 12 months compared with Facebook recruits. No differences were observed

in testing patterns or prevalence of infection in multivariate models, and the prevalence of HIV/STI were similar by recruitment method.

Table 4. HIV and STI prevalence at baseline by recruitment type (Facebook vs Atlanta Venues) and race, InvolveMENT, Atlanta, GA.

Infections	Total			Black			White			Race Interaction	
	Facebook (n=110) n (%)	Atlanta venue (n=693)	<i>P</i>	Facebook (n=34) n (%)	Atlanta venue (n=420)	<i>P</i>	Facebook (n=76) n (%)	Atlanta venue (n=273)	<i>P</i>	<i>P</i>	
HIV (+)	28/110 (25.5)	215/693 (31.0)	.24	13/34 (38.2)	184/420 (43.8)	.53	15/76 (19.7)	31/273 (11.4)	.06	.08	
Rectal STI	2/110 (1.8)	51/693 (7.4)	.03	1/34 (2.9)	45/420 (10.7)	.23	1/76 (1.3)	6/273 (2.2)	1	.56	
Syphilis	11/110 (10.0)	112/690 (16.2)	.09	4/34 (11.8)	99/418 (23.7)	.13	7/76 (9.2)	13/273 (4.8)	.16	.03	

Table 5. Adjusted multivariate models for risk behaviors, testing, and infections at baseline by recruitment type (Facebook vs Atlanta Venues) adjusting for age and race, InvolveMENT, Atlanta, GA.

Characteristics	Ratio measures	<i>P</i>
Risk behaviors^a (ref = Facebook), RR (95% CI)^d		
Total # male partners	0.79 (0.65-0.95)	.01
Main male partners	0.93 (0.74-1.16)	.46
Casual male partners	0.81 (0.65-1.01)	.06
UAI partners	0.56 (0.42-0.73)	<.001
HIV-testing history (ref = Facebook), PR (95% CI)^e		
Lifetime	1.03 (0.96-1.11)	.26
Lifetime ^b	1.05 (0.96-1.15)	.18
Previous 12 months ^b	1.01 (0.86-1.18)	.91
HIV infection and rectal STI^c (ref = Facebook), PR (95% CI)^e		
HIV Infection	0.84 (0.63-1.12)	.23
Rectal STI	1.91 (0.58-6.22)	.21
Syphilis (white MSM)	0.50 (0.21-1.22)	.15
Syphilis (black MSM)	1.92 (0.76-4.85)	.13

^aPartners in the previous 12 months.

^bExcludes participants who were aware of their HIV-positive status.

^cThe prevalence of urethral STI in the cohort was too small to permit analysis.

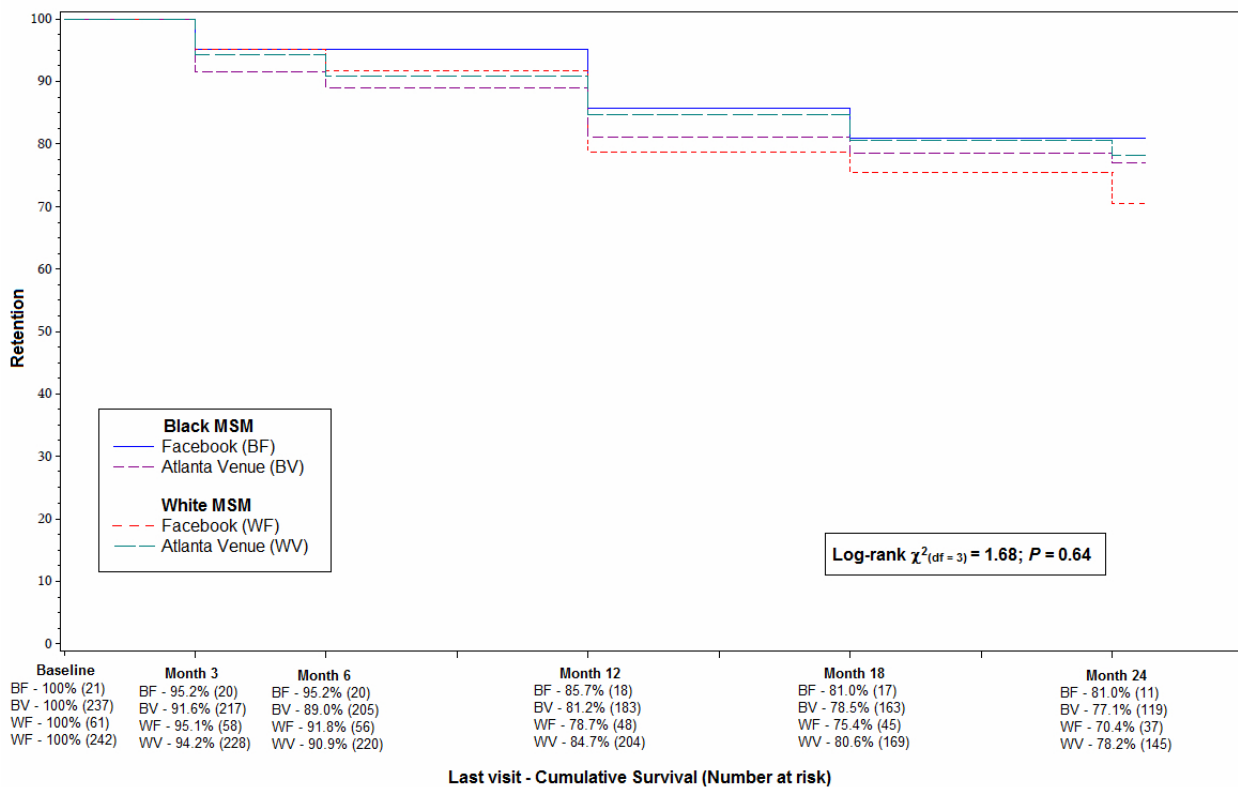
^dModels adjusted for race, age, and HIV-status at baseline.

^eModels adjusted for race and age.

Retention

Study retention by race for Facebook and Venue recruits is shown in Figure 1. A total of 561 individuals were followed prospectively of whom 44.2% (248/561) were black MSM. Race-recruitment method-specific retention to the 24-month

visit estimates were 81.0% for black and 70.4% for white MSM recruited via Facebook, and 77.1% for black and 78.2% for white MSM recruited at venues. There was no statistically significant difference in retention among the four groups (log-rank $P=$.64).

Figure 1. Study retention by recruitment type (Facebook vs Atlanta Venues) and race, InvolveMENT, Atlanta, GA.

Discussion

Principal Findings

Comparing Facebook and VBTS samples of MSM, we observed substantial real-world venue attendance and comparable levels of HIV-testing history and prevalent HIV/STI, with some differences in risk behaviors. We found no difference in 24-month retention rates between recruitment methods. Additionally, cost per screening completed and per study participant were lower for Facebook relative to VBTS. Our findings indicate that recruiting through Facebook may yield comparable samples with those obtained by current VBTS recruitment with similar retention and at a lower cost.

Most Facebook users in our sample visited at least one Atlanta venue where VBTS recruitment might take place, with lower venue attendance rates among black MSM. This corroborates previous findings by Sanchez et al [23], who reported that 95% of MSM recruited online had visited a venue in the last year, with lower rates among minority MSM. Although these findings support the notion that MSM recruited via Facebook might also have been sampled from Atlanta venues, it is unclear whether Facebook recruits would have participated in the study had they been approached at Atlanta venues. More research is needed to explore whether significant differences exist between MSM recruited via Internet and VBTS in factors motivating them to take part in research studies. Additionally, while 88.2% (97/110) of our Facebook sample had visited a real-world venue in the last month, 60.6% (419/692) of VBTS recruits indicated having used Facebook in the same time period. This difference may be due to the oversampling of certain venues, because Facebook use differed by venue of recruitment; the difference might also

be driven by the higher number of white MSM recruited through Facebook, because they reported lower proportions of Facebook use in the previous month. Nevertheless, previous research has shown that there are significant differences in samples obtained at different venues [36], the expansion of this research to differences in the use of social media among different samples of MSM may provide insight into ways of complementing VBTS samples.

Demographic comparisons among white MSM yielded similar findings to other studies comparing online and offline recruitment, in which online recruits were reported to have a higher level of formal education [17,23]. Age differences by recruitment method were only observed among black MSM, with younger black MSM more likely to be recruited via Facebook. Sampling young black MSM is of interest due to the increased number of infections observed in this population [2]. Facebook and other social media may be useful ways to reach these MSM, because they are less likely to be recruited at real-world venues and may be under age for admittance to many gay venues. Regardless, we found that after adjusting for these differences in race and age, there were no systematic biases between VBTS and Facebook sampling in HIV or STI infections or HIV testing patterns. While more research is needed to understand the characteristics of MSM recruited through Facebook, studies seeking to recruit online samples of MSM with specific age or race subgroups may use quota/stratified methods as an alternative to adjust for demographic characteristics of Facebook users [37]. Additionally, certain strategies, such as race-matched banner ads have shown to increase the effectiveness of recruiting online samples of minority MSM [19].

Previous samples of MSM obtained in online chat-rooms and sex-seeking Internet spaces were found to be a higher risk population than MSM attained through VBTS [14,23,24]. In our study, Facebook recruits were more likely to report having visited MSM websites compared with Atlanta venue recruits, indicating that the former may engage in more online sex-seeking behaviors. However, while the higher number of total and UAI partners in the previous 12 months among Facebook supports the idea that they may be a higher risk group, based on comparisons of HIV/STI prevalence, our results indicate no difference in risk between Facebook and Atlanta venue recruits. Additionally, contrary to previous findings, we found that partner serodiscussion and serodiscordance were not significantly different between Web-based and venue samples [17,24,26]. Facebook encompasses a wider range of social interactions than the more sex-seeking focused online environments, as such, it may contain a wider range of risk samples. Therefore, researchers seeking to sample MSM with similar characteristics as those encountered at real-world venues should consider sampling through general social networking sites, while researchers wishing to do studies of higher-risk MSM should consider sampling through online sex-seeking sites.

Our study showed comparable retention rates among all four race-recruitment method groups at 24 months, with no statistically significant difference across groups. Furthermore, retention rates were relatively high relative to a recently reported cohort study [38]. InvolveMENT used a variety of retention-enhancing techniques such as using a custom-built database system that managed participant tracking, scheduling, and communications (including automatically sent visit reminders), as well as routine check-ins from study staff via cell phone, emails, and/or text messaging. Using appropriate and engaging retention methods is paramount regardless of the source of recruitment.

Finally, the average costs associated with recruiting through Facebook were moderately lower than those associated with recruitment via VBTS in terms of cost per completed screening and cost per enrollee in our study. This indicates that studies may potentially recruit MSM more efficiently via Facebook.

Limitations

There are several limitations of this analysis. First, we limited Facebook recruitment to men indicating interest in other men on their profiles. As of April 2014, approximately 1.05% (11,600 out of 1.1 million) of men 18 years of age or older living within a 25 mile radius of Atlanta indicated interest in other men as their sexual orientation of Facebook; this is most likely an underestimate of the number of MSM using Facebook. Our results should be interpreted with caution as our sample is not representative of black and white MSM who do not disclose their sexual orientation in Facebook. Second, the demographic characteristics of MSM recruited through Facebook may change over time. Multiple and repeated samples of MSM using Facebook may be needed to quantify these changes and to ensure the comparability of VBTS and Facebook samples of MSM. Third, we were unable to compare Facebook participants starting but failing to complete the Web-based screening survey to those completing the survey. Fourth, the sample of black MSM recruited through Facebook was small and we therefore had low statistical power to detect differences for the two samples of black MSM and differences between races. Finally, because we used Facebook as a sampling venue and not a sampling frame separate from VBTS, we were unable to compare the effectiveness VBTS and Facebook in recruiting large samples of MSM.

Conclusions

Online social networks such as Facebook may enable recruitment of samples of MSM that are similar to samples attained through VBTS. In our study, VBTS and Facebook recruitment methods yielded similar samples of MSM in terms of HIV-testing history and prevalence of HIV/STI, with no differences in study retention. Surveillance and research studies may recruit via Facebook with little evidence of bias, relative to VBTS, and potentially more efficiently. Furthermore, highly retained samples of black and white MSM may be recruited to traditional prospective studies via Facebook. These findings support the comparability of the two sampling methods, although it is unclear how either method compares with the broader, underlying source population of MSM. Future research should seek to characterize MSM populations that are missed by traditional recruitment methods such as VBTS.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Approximate costs of VBTS and Facebook recruitment, InvolveMENT, Atlanta, GA.

[PDF File (Adobe PDF File), 84KB - [resprot_v3i3e37_app1.pdf](#)]

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Abbreviations

CAGE Scale: CAGE is an acronym of the 4 questions used in the scale (“Cut,” “Annoyed,” “Guilty,” “Eye-opener”)

HIV/AIDS: human immunodeficiency virus/acquired immunodeficiency syndrome

LR: likelihood ratio

MSM: men who have sex with men

NHBS: national HIV behavioral surveillance system

PR: prevalence ratios

RR: risk ratio

STI: sexually transmitted infection

UAI: unprotected anal intercourse

VBTS: venue-based, time-space sampling

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Original Paper

Designing Clinically Valuable Telehealth Resources: Processes to Develop a Community-Based Palliative Care Prototype

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Abstract

Background: Changing population demography and patterns of disease are increasing demands on the health system. Telehealth is seen as providing a mechanism to support community-based care, thus reducing pressure on hospital services and supporting consumer preferences for care in the home.

Objective: This study examined the processes involved in developing a prototype telehealth intervention to support palliative care patients involved with a palliative care service living in the community.

Methods: The challenges and considerations in developing the palliative care telehealth prototype were reviewed against the Center for eHealth Research (CeHRes) framework, a telehealth development model. The project activities to develop the prototype were specifically mapped against the model's first four phases: multidisciplinary project management, contextual inquiry, value specification, and design. This project has been developed as part of the Telehealth in the Home: Aged and Palliative Care in South Australia initiative.

Results: Significant issues were identified and subsequently addressed during concept and prototype development. The CeHRes approach highlighted the implicit diversity in views and opinions among participants and stakeholders and enabled issues to be considered, resolved, and incorporated during design through continuous engagement.

Conclusions: The CeHRes model provided a mechanism that facilitated "better" solutions in the development of the palliative care prototype by addressing the inherent but potentially unrecognized differences in values and beliefs of participants. This collaboration enabled greater interaction and exchange among participants resulting in a more useful and clinically valuable telehealth prototype.

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KEYWORDS

telemedicine; palliative care; delivery of care; home care

Introduction

Given an aging population and changing patterns of disease, health systems are being challenged by an increasing number and type of care needs. Part of the policy response has been to

try to stabilize the demand on hospitals by building capacity in primary care and by supporting care provision in the community. This in turn has driven the need for innovative approaches to facilitate care in community settings [1-3]. Telehealth is gaining increasing prominence within the health system as one solution,

driven by the promise of benefits for patients, their families, health providers, and health services coupled with the possibility of cost savings [4-6]. The possibilities afforded by telehealth in community-based care have led to a rapid expansion of telehealth resources and options [7-11].

Community-based care includes care of patients with palliative care needs. Most patients in the final stage of their life will be cared for in their home for some or for all of this period. Many of these patients will have some form of engagement or interaction with a palliative care service. Involvement with a palliative care service has been shown to improve a person's likelihood of dying at home and to reduce the symptom burden associated with advanced illness [12,13]. While care delivery for patients supported by palliative care services can be structured with a sequenced pattern of contacts or home visits, engagement is not continuous. Patients may decline rapidly or unexpectedly between scheduled visits with little opportunity for proactive intervention by the palliative care service. Patient self-reporting processes with real-time feedback would enable early identification of changes and facilitate targeted clinical and service responses, potentially enhancing care and outcomes. Such self-reporting could be provided through telehealth. Telehealth modules could allow patients to enter information about their symptoms and functional status with algorithms triggering automated clinical alerts based on the data entered. Furthermore, telehealth could potentially support family carers who are integral to enabling the care of palliative care patients at home [14,15]. Some clinical areas have already investigated the possibilities of telehealth-enabled patient self-report in the community [16-18]. These studies have shown a range of potential benefits including increased communication, early intervention, better symptom control, and enhanced patient satisfaction and empowerment. However, the telehealth evidence base within palliative care is more limited [19,20].

The processes involved in developing resources that are clinically meaningful and that interface with, or enhance, work practices are complex and multidimensional. Telehealth resources must satisfy the utility and usability criteria of clinicians and consumers of care as well as meet the policy and system requirements of funders. Telehealth modules may not be successfully deployed where there is a limited understanding of the physical and social structures of the clinical environment and a lack of appreciation of the implications of technical decisions on functional outcomes. Aligning clinical utility within technological capabilities requires consideration of many elements such as:

- the health context and current service delivery model
- what opportunities are enabled by changing practice and by incorporating technological capabilities
- whether knowledge and evidence exists that support both the clinical components and the telehealth choices
- the available technological frameworks and systems
- processes needed to ensure effective and timely decision making
- mechanisms for collaborative resolution of developmental issues
- support for iterative refinement of the telehealth resources before use in research studies and clinical practice.

Resources developed in isolation of the intended use and user, and simply released to the market to determine their potential use and value, may have limited value. However, those that are built to meet only a specific local clinical purpose may be too limited for sustainability and scalability. Westbrook and Braithwaite [21] have argued that there is a need to look at how information and communications technology can be conducted in real clinical settings that acknowledges the complex and collaborative work between colleagues and that involves clinicians from the frontlines in the developmental work. This means that concept selection, prototype design, and construction need to integrate clinical worth and technical feasibility.

A recent review and critical appraisal of eHealth frameworks with respect to the fit between human, organizational, and technological factors has highlighted the interdependent factors underpinning telehealth innovation [22]. The authors noted that while many studies in the review highlighted individual components such as collaboration between developers and researchers or input from users and stakeholders, these components were not reflected in cohesive approaches that collectively enhanced the likelihood of successful eHealth development. Consequently, based on their analysis of the studies, they defined a holistic framework to guide the development of eHealth technologies. Their framework, the Center for eHealth Research (CeHRes) roadmap, is an iterative model that maps the research and developmental activities involved in developing eHealth applications from concept definition through development to summative evaluation. These activities can be described as follows:

- Multidisciplinary project management: facilitates cooperation between those who build the technology and those who are using or affected by it.
- Contextual inquiry: entails gathering information from end users and building an understanding of the environment where the technology will be implemented.
- Value specification: identifies the underpinning value of the various stakeholders to define the critical purposes of the technology intervention.
- Design: assigning and testing the functional characteristics needed to develop a workable and usable prototype.
- Operationalization: deploying the prototype for use and supporting the implementation with training and education.
- Summative evaluation: assessing the effect and the impact of the technology in its environment.

This paper reports on the sequences involved in designing and developing the prototype of a telehealth intervention to support palliative care patients and their carers living in the community. It aims to identify the challenges and considerations in creating a palliative care telehealth prototype mapped against the four formative phases of the CeHRes roadmap, namely multidisciplinary project management, contextual inquiry, value specification, and design.

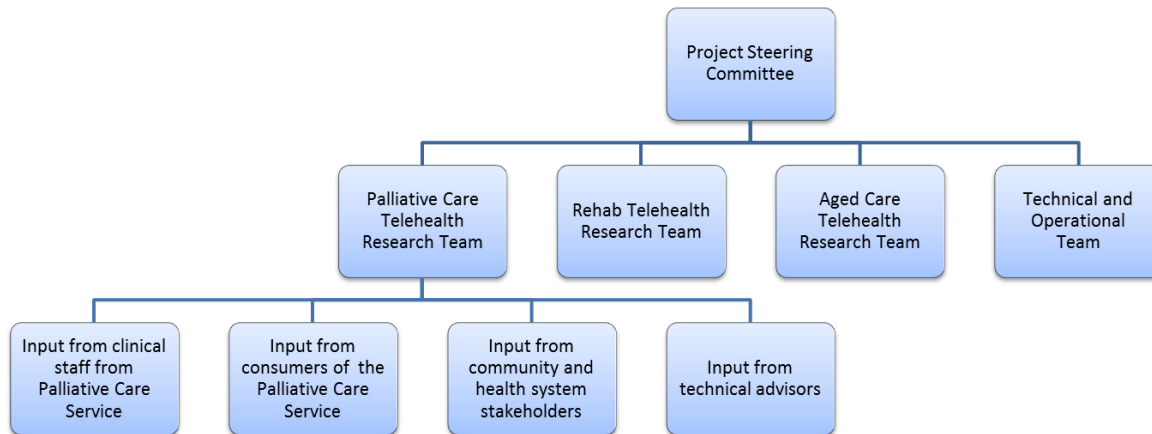
Methods

This palliative care telehealth module was developed as one part of the *Telehealth in the Home: Aged and Palliative Care in South Australia* project, which examined potential benefits

associated with the integration, supplementation, or novel development of telehealth as a key component of care delivery to the home in three clinical care areas (ie, aged care, rehabilitation, and palliative care). Each work stream was led by a clinical research team supported by the project’s technical

and operational team. Ethics approval was gained through Southern Adelaide Clinical Human Research Ethics committee, application number HREC/13/SAC/88(168.13). The whole project was overseen by the Project Steering Committee. Input and reporting relationships are outlined in [Figure 1](#).

Figure 1. Overview of governance relationship and avenues for project input.



Results

Overview

Significant issues were identified in all aspects of the concept and prototype development that reflected the phases and

activities outlined below against the CeHRes model elements. Examples of types of activities and decisions against these four stages for concept ideation and prototype development are included in [Table 1](#).

Table 1. Examples of how inputs associated with research and development activities affected telehealth intervention.

	Concept development	Prototype development
Multidisciplinary project management	Recognizing that a finding from a randomized controlled trial (initiating a case conference at a point of functional decline identified by a standard tool) could be translated into an online app	Opportunities to test and evaluate different technical options for service against multiple criteria
Contextual inquiry	Staff from another eHealth project identified the importance of a Web-based system for data entry	Including a Quality Improvement/usability phase with patients in the community
	Awareness of palliative care service’s previous involvement in clinical studies	Clinicians should not be required to undertake atypical behavior patterns (eg, go to another building for a virtual service)
	Discussions with the clinical team identified that many had no experience with tablets and only limited computer experience in the workplace	Developing required specification of implicit clinical practice
Value specification	Health service providers were facing funding difficulties and hence were supportive of approaches to maintain or enhance community service provision	Assessing trade-offs between device functions and the capabilities of intended users
	Enhancing access to patient and carer’s state of health/well-being between visits	Ensuring continuity of care across patient and carer and pre/post-bereavement
	Supporting clinicians in moving to telehealth	Usability as the priority for prototype
Design	Doing more with less (or same)	“You’re not a geek, it’s ok to not know things”
	Using commonly available devices to support post-trial sustainability	Modifying features based on feedback from patients who assisted in a quality assurance phase
	Recognizing the usability requirements of older people who may have accessibility issues	Remote facility to update carer resources after death of a participant

Multidisciplinary Project Management

The Palliative Care (Telehealth) Research Team (PCTRT) was established to guide the development of a telehealth model for use by the community team of a specialist palliative care service. Membership of the PCTRT included the Director of the Clinical Service, clinical staff (ie, medicine, nursing, allied health), and researchers with expertise in clinical trial design, health services research, and evaluation. A project manager was appointed to support the project development. Input was sought and received during concept and module development from service providers, stakeholders, and patients and carers involved with the service. Meetings were held with the clinicians providing direct care to enable input and feedback on the proposals and the development of the prototype.

The PCTRT had access to, and ongoing support from, members of the Technical and Operational Team who were responsible for the network architecture, systems, and applications used to deliver the telehealth interventions for each of the three clinical streams. The skill base for the PCTRT was enhanced by the inclusion of staff from an associated eHealth project providing access to additional resources and expertise [23].

Contextual Inquiry

The contextual framework for the telehealth intervention was pivotal. Preliminary work on the environment and clinical needs had been undertaken in the process of grant application. Members of the PCTRT were integral to this process. This provided continuity from concept to prototype development and ensured that the original concept idea was rooted in clinical utility. The application process also meant that relationships among potential participants needed to be investigated and established and that key stakeholders needed to be contacted to formalize their support. This provided the prompt for meetings and workshops to explore aspects of telehealth in the local environment.

For those seeking to incorporate telehealth into clinical care practices, being able to use what has been shown to be effective from research in innovative telehealth solutions is critical. While technological innovation in itself may show potentials and opportunities, it is the quality of the clinical content of a telehealth module and its relevance to practice that ensures its value and contribution to the provider and patient community. Several elements of this palliative care module used findings from previous research studies in which the associated clinical service had been involved [24,25]. In effect, this meant that the module used research evidence that improved its clinical value. Further, incorporating the results of this research into the telehealth module offered a mechanism by which the research evidence could be translated for use in practice.

Value Specification

While all stakeholders believed that incorporating telehealth in community service models offered the possibility of enhanced care, there were different views and attitudes on the shape, purpose, and outcomes of such interventions. The meetings and workshops held during the grant application development process facilitated the identification of values held by different participants. This was further explored in meetings held with service staff, technical teams, community members and providers, and funders and stakeholders during project start-up and design activities. For clinical staff, the prospect of enhanced care through more frequent patient-clinician communication, remote monitoring, and change triggers was significant. For the service manager and funders, the capacity to optimize resources while retaining care standards was pivotal. For patients and carers, connectedness through continuous monitoring and videoconferencing was attractive. For researchers and technology developers, the chance to demonstrate feasibility and to assess effectiveness was important. This range of views and attitudes informed the concept design and testing specifications as well as the research and evaluation processes.

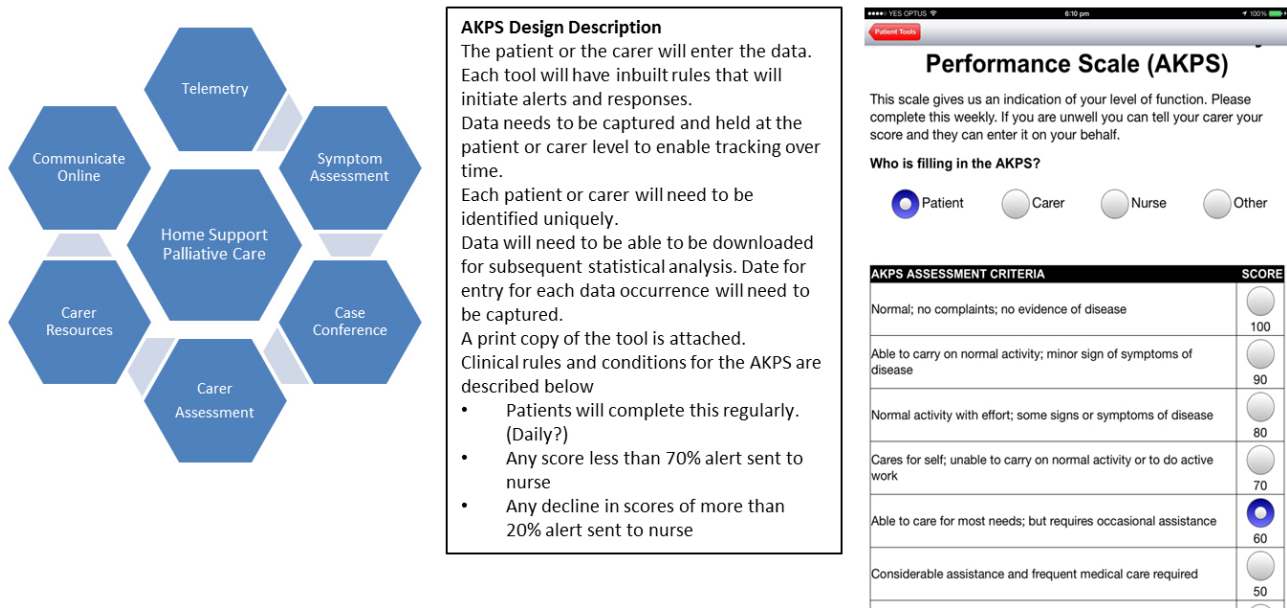
These processes of negotiation and clarification led the PCTRT to realize that, in order to bring about the desired outcomes, the palliative care service needed to see that the telehealth intervention had a direct and real clinical value for the patient and the carer. This central proposition guided a series of decisions during design and prototype testing.

Design

The design process involved careful description of the standard care processes delivered by the palliative care community team and an analysis of how data captured through patient and carer self-report in the community could be integrated into work processes and data systems. This clinical review provided the framework for decision points that needed to be built into the telehealth functionality. While a more detailed technical specification would be developed, this practical specification represented the point of transition between the clinical perception of telehealth as a possibility and the technical production of functional and robust prototypes. Figure 2 outlines the development in the design from initial concept description through clinical articulation to prototype.

While other elements such as the hardware and networks for delivery of the telehealth intervention could be led by the technical team, detailed clinical leadership in defining the characteristics and logistics of the telehealth application during design was fundamental to developing resources that could be acknowledged as valuable in the clinical setting.

Figure 2. Development from concept ideation to functional clinical description to prototype.



Discussion

Summary

The focus of this paper is on the complexity of the environment in which decisions that shape the nature and development of a telehealth concept are made. Moving from idea to application is not linear but iterative, informed by what is learned and what is experienced. Feedback, testing, and incorporation of multiple perspectives can enhance the quality and the utility of telehealth modules. Initial concept decisions that reflect a clear and apparent central value proposition but that respect diversity in values among the stakeholders provide a strong basis in moving from idea to practical resource. This process particularly needs to be shaped by critical input from those who will need to engage with the module, most notably consumers (patients and carers) and health professionals [26]. However, even in initial concept discussions, enabling multidisciplinary participation offers an environment where the relative weight of decisions can be tested and determined, providing some assessment of possible return for effort and technical feasibility. Early engagement with those from a range of discipline-relevant backgrounds and with different roles and experiences helps to adjust the attitudes of participants and build an atmosphere that encourages exchange and inclusion.

The importance of the multidisciplinary team was demonstrated throughout the planning and design work as choices about platforms, devices, and systems all had the potential to affect the experience of both patients and clinicians. For example, the clinical understanding of the functional and cognitive capacities of the patient population became an important element in highlighting the relative importance of simplicity of use for a videoconferencing system over advanced functionalities and security settings. Cost and security options for different approaches were also robustly debated given the implications for post-trial sustainability. These discussions again reflected

different values held by different participants and stakeholders. For example, systems that could engage with hospital record systems could not be deployed for patient use in the community. Provision of tablets rather than self-contained commercial products were seen to offer the best option for service continuation after the trial at the expense of some functionality that could be used by older people with impairments in physical and cognitive function.

Meetings between the PCTRT and the technical advisors also provided a forum where complex problems could be reviewed from clinical, technical, and research perspectives. For example, in palliative care community outreach, death is seen as an expected event. However, the issue of how to handle the effect of the death of a patient within the telehealth environment requires careful analysis. While the telehealth intervention provides support to both the patient and the carer in their home, the death of the patient would mean there is a need to reassess the carer's virtual relationship with the service as well as the carer's experience and use of the tablet in a changed environment, that is, without the presence of their loved one. Various options such as the remote dismantling of the patient resources and/or the enablement of bereavement-specific resources were examined by the PCTRT from the viewpoints of technical feasibility, clinical value, and preferences of the intended user, namely the newly bereaved carer. The resulting dialogue provided the opportunity to illuminate specific aspects of this problem and to examine potential solutions in terms of system capacities and human sensitivities with regard to continuity of relationships and care.

However, while robust discussions about technologies and technical issues were being held at the project level, discussions with the clinical service team identified that many clinicians had no experience and limited confidence in using tablets such as iPads, which were the preferred project device. Early engagement with the clinicians who would be delivering the

telehealth service enabled sufficient lead time for clinical members to be provided with training and experience in using the technology that would be provided to patients. This meant that, at the point where clinical staff began a quality assurance exercise with patients, they felt comfortable in introducing patients to the tablet and the apps contained on them.

The CeHRes framework highlights the implicit diversity in views and opinions that can lead to potential divergence in values and competencies among participants and stakeholders. Such inherent conflict requires those involved in planning and developing to be able to articulate underlying assumptions and be involved in the assessment of the relative importance of different options. Greenhalgh et al's discourse analysis [27] identified conflicting but intersecting discourses on telehealth that reflected different views and values of participants and protagonists in the health sector. Their proposal that learning communities are needed to bridge these gaps reflects the values specification aspect of the CeHRes framework. It also reinforces the need for the initial and ongoing involvement of different parties.

The difficulty is in forming and maintaining teams that can assimilate these varying perspectives and strengthen the developed resources by accommodating technical, clinical, and political complexity. Informed collective decision making assumes that technical, clinical, and social decisions should not be made independently. However, this also implies that participants are able to deal with potentially uncomfortable and unfamiliar sets of knowledge to ensure that these perspectives are integrated. While such team input provides a rich appreciation of the complex nature of the task being undertaken, it also means that there is a need to acknowledge and understand

the expertise and roles of different contributors. The challenges associated with understanding non-shared concepts and terminologies and respecting different processes and paradigms has been previously reported [28]. However, it is also important to acknowledge that establishing working relationships within and across the clinical and technical teams requires a substantial contribution of time and focus. This was challenging in this project as all members of the PCTRT, except the project manager, were participating in the project in addition to their normal clinical and management responsibilities. Tensions associated with positional authority, inability to attend all activities that could influence the design and development of the telehealth modules, and the persistent and detailed analysis and specification required, created pressures for participants and for teams. So, given that the time commitment needed to ensure purposeful engagement and contribution is significant, and recognizing that it is this contribution that drives the contextual inquiry and values analysis, projects need to incorporate this resource requirement adequately into planning.

Conclusions

Telehealth module development is complex and represents a balance between clinical need, consumer benefit, and technical and financial feasibility. A clear health value proposition appears to provide a basis for measurement of different viewpoints and gives clarity to assessing purpose, application, and effect. There may not be a "perfect" answer for any specific telehealth intervention, so the articulation of stages and activities in the CeHRes model that can guide the development and uptake of eHealth provides a mechanism to support "better" solutions that have addressed the underlying, and often unstated, values and beliefs of different participants.

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Conflicts of Interest

None declared.

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Abbreviations

CeHRes: Center for eHealth Research

PCTRT: Palliative Care (Telehealth) Research Team

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Original Paper

Social Networking Versus Facebook Advertising to Recruit Survey Respondents: A Quasi-Experimental Study

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Abstract

Background: Increasingly, social contact and knowledge of other people's attitudes and behavior are mediated by online social media such as Facebook. The main research to which this recruitment study pertains investigates the influence of parents on adolescent alcohol consumption. Given the pervasiveness of online social media use, Facebook may be an effective means of recruitment and intervention delivery.

Objective: The objective of the study was to determine the efficacy of study recruitment via social networks versus paid advertising on Facebook.

Methods: We conducted a quasi-experimental sequential trial with response rate as the outcome, and estimates of cost-effectiveness. The target population was parents of 13-17 year old children attending high schools in the Hunter region of New South Wales, Australia. Recruitment occurred via: method (1) social recruitment using Facebook, email-based, social networks, and media coverage followed by method (2) Facebook advertising.

Results: Using a range of online and other social network approaches only: method (1) 74 parents were recruited to complete a survey over eight months, costing AUD58.70 per completed survey. After Facebook advertising: method (2) 204 parents completed the survey over four weeks, costing AUD5.94 per completed survey. Participants were representative of the parents recruited from the region's schools using standard mail and email.

Conclusions: Facebook advertising is a cost-effective means of recruiting parents, a group difficult to reach by other methods.

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KEYWORDS

Facebook advertising; recruitment; Facebook

Introduction

Social Media and Research

Increasingly, online social media and social network sites mediate social contact and perceptions of other people's attitudes and behavior. There are 728 million people worldwide that use Facebook at least daily [1]. A recent review confirms Facebook's potential for the study of human behavior [2].

Facebook Recruitment

Several recent studies report Facebook as a cost effective and expedient method for recruitment [3-7], though not all enjoy success [8]. Successful approaches vary from Facebook network media and advertising alone to advertising through several search engines and websites. While Facebook advertising is widely used for marketing, and is recommended by some researchers [5-7], it is unclear whether this approach is more

effective than other online or traditional approaches for securing participation in online surveys or forums. No randomized trials have investigated the effectiveness of recruitment through Facebook relative to other approaches.

The Current Research

We are interested in investigating the role of parents in influencing adolescents' alcohol consumption. Engaging parents has historically been a challenge for educators, public health practitioners, and researchers, with low response rates and high attrition plaguing parent- and family-focused interventions [9]. Given the uncommonness of direct connections between parents [10], the pervasiveness of social media use [1], and the success of programs that correct misperceptions about others' drinking [11-13], Facebook may be a useful means of study recruitment and intervention delivery.

This study investigates the efficacy and cost-effectiveness of method (1) social recruitment using Facebook, email-based, social networks, and media coverage relative to method (2) Facebook advertising to recruit parents to complete an online survey. The outcomes are participant numbers, the representativeness of participants, and the recruitment cost per participant.

Methods

Design

We conducted a quasi-experimental sequential trial of recruitment methods, with method (1) initiated first, followed by method (2) in the same population of parents. Inferences about effects are based on the number and timing of responses resulting from methods (1) and (2). It is not possible to measure the response fraction associated with approach (1), as the number of people who were exposed to our recruitment efforts cannot be determined.

Participants

The target population was parents in the Hunter Region of New South Wales (population 644,300), Australia. Eligibility was limited to parents of adolescents 13-17 years old attending the 59 secondary schools in the region. The demographic characteristics of participants are summarized in Table 1.

Procedure

Each of Facebook's network media was used to create an active parent network and to invite parents to complete the survey. The "Hunter Parents Alcohol Forum" (HPAF) was a closed group designed to pilot the use of this approach for intervention. A HPAF Facebook page was designed to attract participants, and a profile ("Hunter PAF") was used for forum discussion and to connect with existing groups and pages. All participants who completed the survey or joined the forum were entered into an iPad prize draw.

Social Network Recruitment and Social Marketing, Method (1)

There were 18 networks likely to include our target population that were identified through Facebook's search function, and connection was established via "friend request", "liking", or "joining". A private message was sent to the administrator introducing the researchers and the project, and requesting they share the survey and HPAF links among their members. There were three of the networks that posted a description and links to the project on their "wall", and we indirectly addressed members of other networks through a public posting on their wall.

Invitations to participate and share the links were circulated via email through our own networks of colleagues, friends, and family. The research was featured twice each in a popular regional newspaper and local radio program at morning and evening "drive-times". An article was featured in a publication with a circulation of 70,000 through regional newspapers. Flyers and recruitment cards were placed in cafes and public places locally, and were disseminated to parents by sporting clubs. There were three clubs that advertised the project in their newsletter. Dr Gilligan spoke at one school's Parents and Citizens Committee meeting and another school posted information about the study on its website and distributed 1000 flyers to parents in a school-fee mail-out.

Materials distributed as part of this approach included brief notices with Web links and scannable codes, flyers and posters more fully explaining the purpose of the study and what parents were invited to do, and longer written pieces about the background to the larger project and its purpose. The content and images varied for each medium used.

Facebook Advertising, Method (2)

To generate a Facebook advertisement, clients select from a series of options for the purpose of the advertisement and pricing arrangement (cost per click or per metric), provide text and images, stipulate the Facebook demographic parameters, and specify a budget and time frame. Cost per click is automatically calculated to optimize the number of clicks in accordance with a maximum set by the user. We produced an advertisement (Figure 1 shows this advertisement) targeting people in the Hunter region (based on postcode), age ≥ 30 years, and whose Facebook profiles indicated that they were parents of children 13-15 years or 16-19 years old (the most relevant available parameters). The advertisement ran for five weeks, immediately following from intervention (1), including an initial trial and several modifications to the advertising parameters. The maximum budget was AUD350 per week, and a cost per click arrangement was used. To assess the impact of the "parents of children" variable depending on accurate profile information, we ran one weeklong advertisement without this limitation.

Figure 1. Advertisement used for recruitment as it appeared on potential participants' Facebook newsfeeds. Text had a 130-character limit.


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Your Teenager And Alcohol
hmrisurveys.hnehealth.nsw.gov.au

**Parents of teenagers
13-17yrs in the Hunter
needed for a Newcastle
Uni study. Win an iPad!**



Results

Comparative Recruitment Rates and Costs

During the eight month social recruitment phase of the trial, 74 people completed the online survey. The main cost of this approach was in research assistant time (AUD4349 for the eight month period based on 10 hours per week dedicated to recruitment efforts), equating to AUD58.70 per survey completion.

Facebook advertising identified a population of 15,900 individuals meeting our eligibility criteria. In the two weeks of active advertising using parent parameters and the final agreed budget framework, the advertisements generated 259 clicks per week (AUD402 total) and 160 survey completions (AUD2.51 per completion). When the “parents of children variable” was removed in an intervening week, the population size increased

to 182,000, but the number of clicks decreased (215 clicks costing AUD344 in total) and survey completions (29 completions at AUD11.90 each) also declined.

In total, AUD1107 was spent on advertising, 840 clicks were generated, and 204 surveys were completed during this period. The cost per completed survey was AUD5.94, including one month of a research assistant wage.

Study Participants and the Parent Population Comparison

Table 1 presents a comparison (for the purposes of assessing population representativeness) between the study participants and the population of parents recruited from three Hunter schools using more traditional postal and electronic mail techniques in a separate study conducted in the same year (Gilligan et al, 2014 unpublished data).

Table 1. Characteristics of parents in this study compared with parents recruited by post and email from Hunter schools in a separate study (assessing sample representativeness).

	Participants in the present study	Hunter schools study
	Total (N=278), mean (SD)	Total (N=444), mean (SD)
Adolescent age	15.44 (1.34)	15.05 (1.43)
Parent age	45.02 (6.07)	46.55 (5.49)
Parent education ^a	2.24 (1.36)	2.26 (1.35)
Adolescent gender, % female (n)	53 (148)	42 (187)
Parent relationship, % mothers (n)	89 (246)	74 (330)
Australian born, % (n ^b)	92 (187)	94 (301)

^aParent education is calculated as a score based on a 0-5 scale from year 10 school certificate to postgraduate education.

^bn for the country of birth variable was 204 for the present study and 320 for the Hunter schools study.

Discussion

Comparative Effectiveness of Recruitment Methods

Facebook advertising was time-efficient and cost-effective for recruiting parents of 13-17 year olds to participate in our study. While specific costs were not attached to the traditional recruitment methods, the researcher time associated with this phase was substantial. In contrast, the development and dissemination of a Facebook advertisement were fast and straightforward. The cost per respondent AUD5.94 was lower than, or similar to, other studies reporting costs of US \$20 [7], US \$4.20 [5], and AUD12 [6] per completed survey or registered participant. (Note, in 2013, AUD1 was approximately equal to US \$1).

The effect size would be over estimated if approach (1) continued to have effects during the implementation of approach (2), and/or that the combination of approaches (1) and (2) is greater than (2) alone. This is judged unlikely given the small effect size of (1) and the rapidity of the onset of a response after (2) was administered. While we did not utilize the “conversion tracking” feature of Facebook advertising, future studies could directly measure website visits resulting from a Facebook advertisement using this feature, which would be a more specific measure of advertisement success than the number of clicks.

Recruitment of large numbers of participants at low cost is a potentially powerful use of Facebook advertising, but the most appropriate target populations and research topics amenable to this type of recruitment should be considered. While Facebook is pervasive, variation exists by age in terms of member numbers and the extent of engagement.

Different Types of Facebook Users

People 35-54 years old constitute a third of Facebook users [1], but based on user types defined by Evans et al [14], this does not equate to the proportion likely to participate in research. Older Facebook users are predominantly categorized as “neutrals” or “gamers”, accounting for 23% and 4% of Facebook users respectively, but with vastly different levels and types of use [14]. Neutrals have low engagement in terms of time spent on the site and frequency of visits, primarily using it to stay

connected and informed about social events. Gamers are the smallest group numerically, but largest in terms of level of use. Evans et al [14] report that the primary motivation for gamers to engage in groups or link with others is the attainment of extrinsic rewards such as coupons and gaming points. Anecdotal evidence from members of the HPAF suggests that the majority of the parents who engaged in that part of the study were gamers. While neutrals may represent a large proportion of our prospective target population, attracting these users to engage in research and networking is challenging.

Considerations for Recruiting Through Facebook

The study populations generated through Facebook are arguably more socially engaged, educated, and higher income groups than the general population. Several studies, however, report successfully recruiting participants that reflect the demographic spread reported in population surveys and census data [3,7]. In our study, the parents who completed the survey had diverse education levels and income, and reflected the population of Hunter schools in terms of demographics and ethnic diversity. In epidemiological analysis, diversity in the exposures of interest is more important than representativeness in estimating associations with outcomes [15].

An important consideration highlighted by our trial is the trade off between specificity and reach. Many potential participants may not have current or detailed profiles, such that they do not receive targeted advertising. More relaxed parameters increase the likelihood that an advertisement will be viewed by members of the target population, but decrease cost-effectiveness. It is possible that the pattern of response reflects the relationship between the relevance of an advertisement for an individual and their likelihood of responding. We found stricter parameters more economical in terms of the clicks/survey completions trade off.

The restrictive geographic inclusion criteria we used limited our participant numbers. Facebook recruitment approaches may be most appropriate for targeting large geographically and demographically diverse population groups, or for identifying highly targeted groups based on specific inclusion criteria associated with their profile or location.

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Conflicts of Interest

None declared.

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Abbreviations

HPAF: Hunter Parents Alcohol Forum

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