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Feasibility and implementation of a healthy lifestyles program: A pragmatic mixed methods pilot study

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ABSTRACT

Introduction

Rates of chronic conditions, such as diabetes, obesity and depression are increasing in Canada and internationally. There are effective lifestyle interventions that are known to improve chronic conditions. However, there is often a gap in "how to" make these changes. Mental health and other determinants of health play a role in the development and progression of chronic conditions. While many studies continue to look at the effects of lifestyle modifications, it is just as important to develop programs that encourage individuals to adopt healthier lifestyles. Changing habits takes time and requires the use of multiple techniques based on patient needs. A new, multidisciplinary, person-centered, holistic and evidence- and practice-based program has been created to address these needs. This proposal aims to evaluate the feasibility and implementation of this program and to determine changes in participant-directed and clinical outcomes through a pilot study.

Methods

A pragmatic mixed methods design will be used to study multiple dimensions of the year-long healthy lifestyles program. The pilot study includes a randomized controlled trial and qualitative components to determine the feasibility of the program, including recruitment and retention, data completion rates, and resources needed to run this program. Changes in participant-directed and clinical outcomes will be measured. Regression and multivariate analyses will be conducted. Qualitative interviews of program staff and healthcare providers and family focus groups will be used to further enhance the findings and improve the program. The RE-AIM framework will be used to guide the analyses.

Ethics and Dissemination

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. Informed consent will be obtained prior to enrolling any participant into the study. All data will be kept confidential. Peer-reviewed publications and presentations will target researchers and health professionals.

Trial registration ClinicalTrials.gov Identifier: NCT03258138
Hamilton Integrated Research Ethics Board (HiREB) project number: 3793

Strengths and limitations of this study

- Integration of quantitative and qualitative data are used to holistically evaluate the two programs.
- The study evaluates a complex intervention for behaviour change incorporating mental health strategies.
- Research methodologies are combined to maximize learning from this study.
- It is a pragmatic study, which allows for a wider range of participants to be studied and increases the external validity of the results.
- The staff and participants are not blinded to the intervention.
- The study is not adequately powered, although since this is a pilot study, this information will be used to inform a larger randomized trial.

BACKGROUND

Rates of chronic conditions, such as diabetes, obesity and depression, are rising in Canada and internationally.(1–6) These chronic conditions can, on their own or as co-morbidities, impact the quantity and quality of people's lives.(3,7,8)

There are simple, yet effective, lifestyle (e.g., behavioural) interventions which are known to improve symptoms of many chronic conditions. These interventions include eating a healthy diet, having sufficient sleep, improving socialization, quitting smoking, managing stress, and being active, among others.(9,10) Even though some of these lifestyle changes are well-known, there is often a gap in "how to" make these changes. Mental health also plays a role in the ability to seek out and follow through on the changes necessary to achieve or maintain a healthy lifestyle, yet this aspect is rarely addressed in chronic disease self-management or weight-loss programs. Cognitive behavioural therapy (CBT), in particular, has been shown to help with weight loss, insomnia, anxiety and depression.(11–14) In 2012, 1 out of every 3 Canadians met the criteria for mental or substance use disorder at some point in their lives.(15) Yet, access to mental health services is limited in Ontario by a lack of providers and non-coverage of services by the Ontario Health Insurance Plan (OHIP).(16,17)

Furthermore, individuals are shaped by the society in which they live. Determinants of health, such as income security and the built environment, play a role in the development and progression of chronic conditions. Determinants of health can also act as barriers to achieving healthy lifestyles (e.g., lack of socialization, unsafe neighborhoods). There is not enough time in a regular office visit to address a whole range of possible individual barriers, and physicians do not always have the training to deal with all of these issues.

Person-centered care

Changing habits takes time and requires the use of multiple techniques based on patient needs. This type of person-centered care is a different approach than simply bringing more services to one location, or having services follow individuals.(18–20) This approach starts by attending to the needs of the individual (e.g., improving mood, finding motivation) instead of the pre-set indicators typically used to determine success in the clinical care of chronic conditions (e.g., lipid levels, smoking cessation). The hypothesis is that approaching problems from the individual's perspective and providing the tools, skills and supports to meet self-identified goals, will lead to more sustainable improvements in health-related quality of life, which in turn lead to improvements in clinically-relevant indicators.

Using these techniques is not mainstream in the clinical setting and few individuals have access to behavioural therapists. Furthermore, many current programs address only one condition or patient population, have limited involvement with trained health providers, focus only on secondary or tertiary prevention, or neglect the role of mental health or the social determinants of health in lifestyle changes.(21–23) A new, multidisciplinary, person-centred, holistic and evidence- and practice-based healthy lifestyles program has been created to address these needs. This proposal aims to evaluate the feasibility and implementation of the healthy lifestyles program through a pilot study.

MAIN RESEARCH QUESTION AND STUDY HYPOTHESIS

Does a year-long healthy lifestyles program (holistic program based on CBT and behavioural theories provided through group and individual sessions) along with usual care (more intensive program or MIP) compared to development of health goals along with usual care (less intensive program or LIP) help meet participant-directed and clinical outcomes for adults? We hypothesize that the MIP will be feasible and more effective for helping participants move across stages of change and for meeting goals than the LIP.

OVERALL GOALS AND OBJECTIVES

The goal of this pilot project is to determine the feasibility and implementation of the full healthy lifestyles program (MIP). This pilot study will also identify the conditions for a larger randomized controlled trial. Evaluating the context of this pilot phase will help determine if, and how, the program should be considered for scaling up in other parts of Canada and/or internationally. The control group will help determine

if the LIP is just as useful, keeping in mind these are small numbers, so findings cannot be generalized from this study. See Table 1 for study objectives, analysis plan and outcomes.

Primary objective:
To study the feasibility and implementation of the MIP

1) To assess the feasibility of recruitment, retention, attendance in group and individual sessions, and completion of data
2) To assess resources needed to run the MIP, including the type and mix of health professionals, numbers and sizes of rooms for group and individual sessions, materials, costs and medical utilization
3) To obtain feedback from multiple stakeholders, including participants, staff, family members, and other health providers in order to improve the healthy lifestyles program and to determine its acceptability

Secondary objectives:
To determine changes in participant-directed and clinical outcomes

1) To determine changes in participant-directed outcomes through goal development and associated measures
2) To determine changes in clinically relevant outcomes, such as health-related quality of life, anxious and depressive symptoms, sleep, loneliness, stress, other health indicators (HgA1C, fasting lipids, and complete blood count (CBC) and measurements (blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Scale

Table 1. Study objectives, outcomes and analysis plans

Objectives		Outcomes	Analysis	Hypothesis
Primary				
Assess implementation and feasibility	Assess feasibility of recruitment, retention, group size and data completion	Recruitment and retention rates, attendance per session, missing data	Descriptive statistics	The Healthy Lifestyles Program is feasible and acceptable
	Assess resources needed to run program	Health professionals needed, numbers and sizes of rooms needed for group and individual sessions, materials needed, costs and medical utilization logs	Descriptive statistics, cost analyses	
	Participant feedback	Patient satisfaction surveys	Descriptive statistics and thematic analysis for open-ended questions	
		Qualitative exit interviews	Thematic analysis	
	Staff feedback	Staff interviews	Thematic analysis	
	Family member feedback	Family focus groups	Thematic analysis	
	Healthcare provider feedback	Healthcare provider interviews	Thematic analysis	
Secondary				
Participant-directed outcomes	Assess the development of and progression of participant-directed goals	Goal development and measures	Change in individuals over time and between and within group comparisons; Descriptive statistics, regression and multivariate analyses will be conducted to the extent possible	The intervention group will show greater movement in stage of change and in meeting goals
Clinical outcomes	Health-related quality of life, anxious and depressive symptoms, sleep, loneliness, stress, and other health indicators (HgA1C, fasting lipids, and CBC as dictated by current guidelines), blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Scale (if relevant)	Rate of completion and outcomes of scales and other measures	Change in individuals over time and between and within group comparisons; Descriptive statistics, regression and multivariate analyses will be conducted to the extent possible	The intervention group will show greater improvement in these measures

METHODS

Study design and participant involvement

The current study uses multiple designs (pilot study, pragmatic trial, mixed methods study), and this protocol combines the conventions used by each, as previously done by Samaan et al.(21) This study design allows for the flexibility needed to study multiple dimensions of a new program, especially one designed for creating healthy lifestyles through the development of participant-directed goals and individualized action plans.(24–27) This study includes elements of both concurrent and embedded mixed methods designs. This allows for both quantitative and qualitative data to be used to better inform aspects of the program, while also allowing for different research questions to be asked that require different types of data that link up at multiple points of the study.(27) For example, the embedded design will allow for qualitative data to be collected to add depth to the quantitative empirical findings, to answer questions around the process of implementing the programs, and to test and inform the programs.(28)

This study is not blinded as the amount of exposure to the programs will be known to participants and providers. It is pragmatic in that it is being conducted in a real-life setting with few criteria for exclusion, which allows for a wider range of participants to be studied and increases the generalizability of findings (see figure 1).(24) This study proposes a first stage that examines the feasibility and implementation of the intervention. These findings will inform other stages of the study and the evaluation of a larger, scaled-up, intervention. For example, sample sizes will be determined for a randomized controlled trial based on effect sizes found through this pilot phase.

The qualitative components include semi-structured exit interviews of participants (at 12 months), MIP staff and participants' healthcare providers (at 6 months and 12 months). In addition, focus groups will be conducted with family members of MIP participants at 9 months. These elements will provide perspectives from multiple stakeholders for improving the healthy lifestyles program and on their roles in creating and maintaining healthy lifestyles. The pragmatic design was, in part, chosen to allow for the interviews and participant satisfaction surveys to be used to make changes to the programs, or their delivery, while the study continues.

Patients with chronic conditions were part of the pre-trial test run of the program and helped develop the protocol as collaborators. As a person-centered program, the participants are involved in the development of relevant personal goals and their scales. They also provide feedback on the program throughout the study through participant surveys. This feedback is used pragmatically to shape the program during the study, if needed, to fit participants' needs. Any changes made will be noted in the final report. All collaborators will be invited to review the results and determine implications of these findings for future practice and research.

Novel intervention

Each individual will be enrolled in the healthy lifestyles program for one year. This amount of time allows for determination of participant goals, identification of barriers and facilitators, healthy lifestyle education, and modification of individualized action plans. Participants will meet weekly for group health and wellness learning sessions or brainstorming group sessions. The health and wellness learning sessions provide a platform for concepts from a variety of health behaviour theories and CBT to be combined with evidence- and practice-based recommendations for healthy lifestyles.(11,29–32) These provide the basis for the individualized action plan. Monthly individual sessions with a family physician trained in medical CBT, a dietician and a physical therapist help individuals tailor their action plans to their particular circumstances and needs.(33,34) The group sessions allow for facilitated discussions where individuals explore barriers and facilitators to achieving their goals and provide an interpersonal component to the program. Participants will also receive help in finding community programs to support healthy lifestyles.

An ecological approach to behavior change will be used throughout the program, which allows for the inclusion and assessment of factors at the individual, interpersonal, institutional or organizational, community and policy levels.(30) In addition, Prochaska's stages of change, or transtheoretical model, is used to track and measure changes of participants in each of their health goals.(35,36)

Preliminary evidence to support this approach

Modified versions of this program have been used in presentations to graduate students on stress management,(37) time management,(38) and in classroom settings through a Theories of Health Behaviour course taught by the principal investigator at McMaster University. In addition, a pre-trial test run (Summer 2017) with nine individuals enhanced the style of delivery, format and content of the health and wellness learning sessions and the initial assessment segments of the program. Feedback from the pre-trial test have been positive for the content and structure as well as for reinforcing the ability of the program to address gaps in current care.

Two Arms of the Study

The current study contains two arms; an intervention group, or more intensive program, and the control group, or the less intensive program. Both arms will continue to receive usual care as provided by their healthcare practitioners. If there are any significant changes to an individual's health status, these will be communicated to the family physician with participants' consent.

Intervention group = usual care + healthy lifestyles program = more intensive program (MIP)

Table 2 provides a more detailed listing of components for the program and its related research activities. Intervention group participants will receive the full healthy lifestyles program with weekly group sessions and individualized monthly meetings with team members (as described in the 'novel intervention' section).

Control group = usual care + health goals = less intensive program (LIP)

Individuals in the control group will develop health goals with the support of a research assistant trained in theories of health behaviour. However, the "how to" put these goals into practice will not be provided as the means to test the healthy lifestyles program.

Table 2. Components for healthy lifestyles program pilot study

Time	Intervention group= More intensive program (MIP)= usual care + healthy lifestyles program	Control group= Less intensive program (LIP)= usual care + health goals
Recruitment and selection; randomization; enrollment		
Week 1	S1; C&MU; PAJ	DC/L&M, Scs; C&MU; PAJ
Week 2	S2, Scs; NJ	NJ
Week 3	S3	
Week 4	S4; IA, DC/L&M	
Week 5	S5	
Week 6	S6	
Week 7	S7	
Week 8	S8; F/U	
Week 9	BG	
Week 10	BG; PAJ	PAJ
Week 11	BG; NJ	NJ
Week 12	S9, Scs; F/U; DC/L&M, PSSI, C&MU	DC/L&M, Scs, PSSC, C&MU
Week 13	BG	
Week 14	BG	
Week 15	BG	
Week 16	S10; F/U	
Week 17	BG	
Week 18	BG	
Week 19	BG	
Week 20	S11; F/U	
Week 21	BG	
Week 22	BG; PAJ	PAJ
Week 23	BG; NJ	NJ
Week 24	S12, Scs; F/U; DC/L&M, PSSI, C&MU; SI, HCI	DC/L&M, Scs, PSSC, C&MU
Week 25	BG	
Week 26	BG	
Week 27	BG	
Week 28	S13; F/U	
Week 29	BG	
Week 30	BG	
Week 31	BG	
Week 32	S14; F/U	
Week 33	BG	
Week 34	BG; PAJ	PAJ
Week 35	BG; NJ	NJ
Week 36	S15, Scs; F/U; DC/L&M, PSSI, C&MU; FFG	DC/L&M, Scs; C&MU
Week 37	BG	
Week 38	BG	
Week 39	BG	
Week 40	S16; F/U	
Week 41	BG	
Week 42	BG	
Week 43	BG	
Week 44	S17; F/U	
Week 45	BG	
Week 46	BG; PAJ	PAJ
Week 47	BG; NJ	NJ
Week 48	S18, Scs; F/U; DC/L&M, C&MU collected, EI	DC/L&M, Scs, C&MU collected, EI
Week 49	EI, SI, HCI	
Week 50	Ceremony	

Legend: S – Session (1hr); S1 – Introduction to Program; S2 – Identifying health goals; S3 – Healthy mindsets and stress management; S4 – Creating a life compass; S5 – Building resources; S6 – Active lifestyles; S7 – Healthy nutrition; S8 –

Identifying and overcoming barriers; S9 – Finding motivation; S10 – Living your values and addressing life changes and adversities; S11 – Advanced stress management techniques; S12 – The self within us; S13 – Building healthy relationships; S14 – Advanced time management techniques; S15 – Increasing self-efficacy; S16 - Increasing your social circle; S17 – Mental wellbeing and chronic pain; S18 – Revisiting goals and reflecting on self-growth; BG – Brainstorming group session (1hr); PAJ – Physical activity journal; NJ – Nutrition journal; Scs – Scales, including The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+), quality of life scales (SF-36 and HUI2/3), Patient Health Questionnaire (PHQ), Insomnia Severity Index (ISI), Perceived Stress Scale, Life Change Index Scale, and DeJong Gierveld 6-item Loneliness Scale, PSSI- Participant satisfaction survey intervention arm, PSSC- Participant satisfaction survey control arm; C&MU – Costs and medical utilization log; IA – Individual initial assessment (3hrs); F/U – Individual follow-up visit (1hr); DC/L&M – Data collection form with labs (HgA1C, fasting lipids, and CBC as dictated by current guidelines) and measurements (blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Scale (if relevant); EI – Exit interview; SI – Program staff interviews; FFG – Family focus groups; HCI – Healthcare provider interviews; Ceremony – provided for participants and family/friends along with certificate of completion of the Program.

Setting

This study will be conducted through McMaster University, and the site of the study will be at the David Braley Health Sciences Centre, Hamilton, Ontario.

Training of health professionals and research staff

The health professional leading the intervention is a family physician with training in medical CBT. The dietician and physical therapist are fully licensed. Research assistants will have training on research ethics and other aspects of data collection and analysis. Training will be provided on how to support participants in the LIP to identify goals. It will also be provided on how to conduct participant interviews and focus groups, and how to maintain field notes. Facilitators for the brainstorming sessions will have training on how to lead facilitated sessions and on conflict management.

Sampling and recruitment

Participants in the randomized trial will include English-speaking individuals 18 years of age or older. Participants must be able to engage in the group sessions and understand and sign the informed consent form. Fifteen participants will be recruited for each arm of the randomized trial. This number accounts for ideal numbers of people involved in small group sessions based on practice experience and for potential attrition throughout the year.(8–15) Posters will be placed in doctor's offices with the consent of the staff. Potential participants will be approached by a research assistant during an office visit, who will describe the purpose of the study and answer participant questions. Posters will also be placed in community settings, such as office buildings, after obtaining consent from that facility.

The research assistant will obtain consent and enroll participants into the study. A participant maintains the right to drop out of the study at any time without consequences to her/his care. However, the numbers and reasons for dropping out of the study will be sought and noted as part of the program evaluation.

Sampling and recruitment for qualitative components

All participants and MIP staff will partake in semi-structured interviews. If consent is given by participants, healthcare providers involved in the participant's care outside of the study will be approached to participate in semi-structured interviews. Family focus groups will include family members, who are 16 years of age or older and English-speaking, of participants in either arm. Outreach to family members will occur through participants. Informed consent will be obtained prior to the interviews or focus groups.

Allocation and randomization

Each participant will be assigned a random number using the RAND function on Excel. Participants will be allocated to the MIP or to the LIP in a ratio of 1:1, starting with the lowest number. If two participants are in a relationship, then they will be placed in the same group based on who is randomized by the lowest number. A research assistant not involved in the recruitment or in the programs will allocate the participants.

Data collection procedures

Paper-based and electronic measures will be used to collect data. See Table 3 for a list and description of instruments used in the pilot study. For the MIP arm, charts will be reviewed when possible to gather data, such as the initial assessment, action plans, labs and measurements. The rest of the data for the MIP arm and all the data for the LIP arm will be collected through face-to-face individual meetings. With the support of the MIP team or the research assistant for the LIP group, participants will identify relevant health goals and define how to measure these goals on a 1-7 scale, with 1 being the "worst case," 7 being the "best case," and

4 being the "middle." Therefore, the measurements will also be participant-relevant while allowing for a variety of goals to be measured. In addition, scales for motivation, stages of change, and self-efficacy are included for each goal. If labwork information is not available, participants will be asked to have labwork drawn if they meet current screening guidelines. For HgA1C and lipids, this includes being 40 years of age or older or having risk factors as outlined in the guidelines for diabetes and cardiovascular disease, respectively.(39,40) A complete blood count (CBC) will only be conducted if the participant has symptoms, such as fatigue, or a history of cancer, infections or blood disorders as determined by the clinicians involved in the study. Measurements include blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, and Edmonton obesity scale (if relevant).(41)

Participant satisfaction and feedback will be assessed through surveys at 3, 6 and 9 months. Weekly nutrition journals and physical activity journals and a costs and medical utilization log will be provided to participants and collected once every three months. Worksheets for each health and wellness learning session will be provided for participants in the MIP group only, which will not be collected for study purposes.

For research purposes, the pilot involves the use of two generic and a number of specific measures of health status and health-related quality of life. The routine application of the intervention would involve a more parsimonious set of measures. Validated health and wellbeing scales will be filled out by participants at baseline and every three months to assess change in these indicators (five times total). The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) will only be filled out at baseline to ensure goals related to physical activity are appropriate given a participant's health status. The rest of these scales were selected for addressing a holistic range of mental health indicators that are dealt with in the healthy lifestyles program. The RAND SF-36(42,43) and HUI 2/3(44–46) are validated instruments for health-related quality of life indicators. The decision to use both is to compare findings from these instruments. The Patient Health Questionnaire (PHQ) is made up of five domains to evaluate for depression (PHQ-9), anxiety (GAD-7), bulimia, somatoform disorders and alcohol misuse.(47–49) The Insomnia Severity Index identifies insomnia symptoms.(50) The Life Change Index Scale, otherwise known as the Holmes and Rahe stress scale, has been found to correlate with medical utilization in a family practice setting.(51) In addition, the Perceived Stress Scale measures the degree to which situations in one's life are perceived as stressful.(52,53) Lastly, the DeJong Gierveld 6-item Loneliness Scale captures both emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network).(54,55)

Administrative data will be used for adherence information (e.g., number of participants attending each education session) and for data on costs of running the programs.

Qualitative data collection

Interviews and focus groups will be recorded with a digital recorder and transcribed. Field notes will be taken during these interviews and focus groups to describe the setting and keep track of other events. Data will be entered into the relevant software (Excel, SPSS, NVivo) by research assistants. All information will be kept confidential and participants IDs will be used whenever data is coded.

Table 3. Pilot study instruments

Instrument	Purpose	Administered	Time to complete (min)	Timepoints Intervention	Timepoints Control
Enrollment form	To obtain contact information and preferences, emergency contact information, and sharing of information with primary care provider	Self	5	Baseline	Baseline
Data collection form	Baseline data and to measure changes over time on patient characteristics, health conditions, health habits, labs, measurements, goals and their attainment	Research assistant as chart review and in individual meetings with participants	120 60	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo, 12mo
Physical activity journal	To track usual physical activity over a week and over time	Self	20-30/ week	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Nutrition journal	To track usual eating content and habits over a week and over time	Self	30/week	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Health and wellness learning session worksheets	To reflect on personal habits and reasons for change	Self	5- 30/week	In health and wellness learning sessions and for reflection between sessions	
Action plan and barrier identification	To develop personalized plan for sustainable lifestyle changes and to identify barriers	Team members and participants	Initial 45-60; Follow-up 10-15	Monthly in individual sessions	
PAR-Q	Physical activity readiness	Self	10	Baseline	Baseline
SF-36, HUI2/3	Quality of life	Self	12-15	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Patient Health Questionnaire (PHQ)	Baseline and change over time for depression and anxiety	Self	10	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Insomnia Severity Index (ISI)	Baseline and change over time of insomnia	Self	5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Perceived stress scale	Baseline and change over time of perceived stress	Self	2-5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Life Change Index Scale	Baseline and change over time of stressors	Self	2-5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
DeJong Gierveld Loneliness Scale	Baseline and change over time for loneliness	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Participant satisfaction surveys	To measure participant satisfaction and improve program	Self	10	3mo, 6mo, 9mo	3mo, 6mo, 9mo
Costs and medical utilization log	To measure direct costs and medical utilization	Self	10-30	Continuous	Continuous

Data analysis

Quantitative

See Table 1 for a description of the objectives of the study, outcomes measured, and analytic techniques for each component. Quantitative data will be reviewed for completeness and entered into Excel and/or SPSS. Descriptive statistics will be presented for the participants in the study. Changes within individuals over time, and differences within and between groups will be assessed. Regression and multivariate analyses will be conducted to the extent possible, realizing this pilot phase constitutes a small sample. Since this is a pilot study, this information will be looked at to help inform a larger randomized trial and statistical significance will not be sought. Total costs and cost-effectiveness analyses will also be conducted to the extent possible.

Qualitative

Transcripts, field notes, and documents will be entered into NVivo and coded. Concepts and themes will be developed using a constant comparative method of analysis in which new information is compared to previous information. Themes related to the concept of the programs, implementation of the programs and feasibility will be developed, among others. Confirming and disconfirming evidence will be sought to ensure data saturation or completeness of the findings.(56)

Data and participant monitoring

Team members will meet weekly to discuss study progress and review data quality and monitoring of attendance or any concerns raised by participants or clinicians.

Participants will fill out mental health scales, which will be scored during their visits. If any concerns around these findings or other signs of deterioration are encountered by anyone on the research or program teams, the principal investigator or alternate clinician will be notified while the participant is still in contact with the team member. An assessment will be conducted and if any concerns arise for self harm or harm to others, proper guidelines will be followed, including creating a safety plan, contacting the participant's family physician and/or providing more frequent follow-ups, or contacting emergency services, as deemed appropriate.(57)

Few risks are anticipated for this study. However, there could be anxiety or fatigue caused by participating in the study or in filling out the forms. If any concerns are noted, the principal investigator will attend to these concerns and may remove the participant from the study, following a discussion with the participant and the team, if this is deemed in the participant's best interests. This study does not require a data and safety monitoring board since there are no drugs or devices being tested and is considered low risk.

Timeline and activities and knowledge translation

The pilot phase will take approximately 24 months (beginning in April 2018 and ending in April 2020), which includes time for recruiting participants, planning logistics, running the full programs, analyzing data, and generating knowledge translation activities. Knowledge exchange will include feedback from participants, staff, health providers and family members. Peer-reviewed publications and presentations at conferences (e.g., family medicine, public health) will target researchers and health professionals. Policymakers and other stakeholders will be engaged to identify needs and any policy implications of the findings.

Ethical considerations

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. If any changes are made to the research design, HiREB will be notified and changes will be made based on their

recommendations. A research assistant will approach potential participants to explain the nature of the study, their rights as participants, confidentiality of their data, voluntary entry into the study, and their ability to withdraw from the study at any time.(58,59) There is minimal risk of entering this study, however, participants will be informed about the potential risks of unintended disclosure, where they may potentially give away information about themselves or about a third party which could lead to recognition of themselves or the third party (in which case confidentiality will be sought for the third party as well). In addition, there are some risks to starting or increasing any exercise activity, such as injury. However, the benefits of increasing mobility outweigh most of the risks of potential injury and having trained team members and setting realistic goals will allow for gradual adjustments in their mobility levels. Any questions will be answered, and informed consent will be obtained prior to enrolling any participant into the study. All data gathered for the study will be kept confidential by using identifiers (with identifiers and identifying data kept separately), and access will only be given to the research team members. Paper documents will be stored in a locked cabinet. Electronic documents will be kept on password-protected computers.

Incentives – Participants will receive a modest monetary compensation each time they meet with the research assistant for data collection every three months (5 times total). Control-arm participants (less intensive program) will be allowed to participate in the healthy lifestyles program (MIP) at a later date on the condition that the program is still running.

Post- trial care

Participants will continue to receive usual care from their primary care physicians during and after the study.

DISCUSSION

This pilot phase is to assess the feasibility and implementation of the full healthy lifestyles program. However, in the longer-term, findings of this and future research in this area are expected to address gaps in knowledge around individuals' attainment of healthier lifestyles, on health services organization, and on community and policy efforts to support these changes. The impact on participant experiences and outcomes is one of the main objectives of this study. The healthy lifestyles program is person-centered in that it allows for participants to self-identify relevant health goals and to develop realistic and sustainable action plans to achieve their goals. The purpose of evaluating the healthy lifestyles program is to understand if and how it works, to iteratively improve the program, and to understand the implementation process so that it can be scaled up successfully in other sites.

List of abbreviations

BMI – Body mass index

CBC – Complete blood count

CBT – Cognitive behavioural therapy

FHTs – Family health teams

HiREB – Hamilton Integrated Research Ethics Board

HUI – Health Utilities Index

LIP – Less intensive program

MIP – More intensive program

OHIP – Ontario Health Insurance Plan

PAR-Q+ - Physical Activity Readiness Questionnaire for Everyone

PHQ – Patient Health Questionnaire

RAND SF36 – 36-Item Short Form Survey

Declarations

Ethics approval and consent to participate

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. Project number: 3793

Competing interest

D.F. has a proprietary interest in Health Utilities Incorporated, Dundas, ON, Canada. HUI Inc. distributes copyrighted Health Utilities Index (HUI) materials and provides methodological advice on the use of the HUI. The other authors declare no conflict of interest.

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Author's contributions

EA developed the research question and protocol. EA and MQ drafted the manuscript. All authors contributed to the design of the protocol and read and approved the final manuscript.

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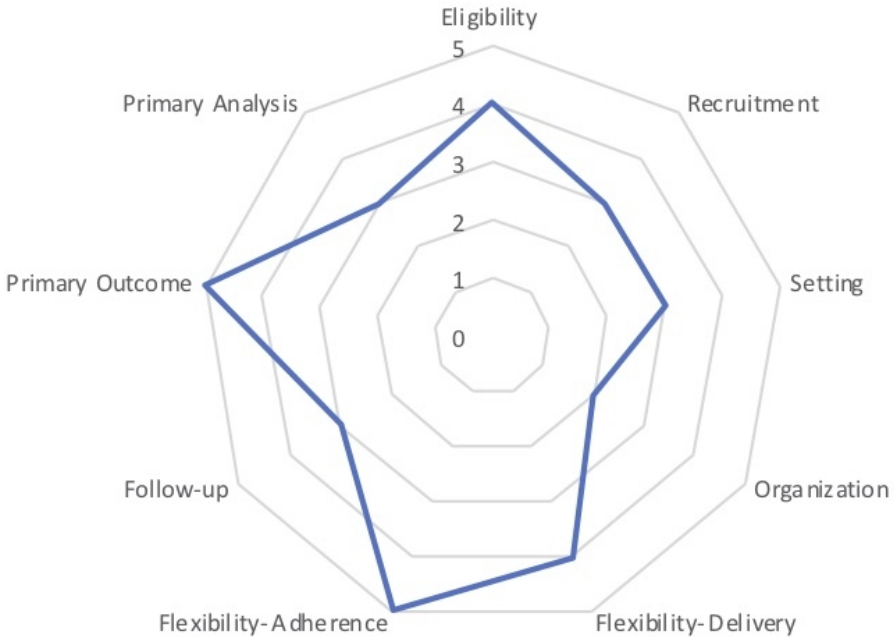
Figure 1 Legend:

Figure 1. PRECIS-2 wheel for the healthy lifestyles program trial design. This figure was created by reaching a consensus for each domain from four investigators on the study team using a 1 to 5 ordinal scale from explanatory (blue line towards the centre) to pragmatic (blue line towards the periphery).(60) Aside from the *organization* domain, the PRECIS-2 wheel illustrates that the study design is closer to a pragmatic than an explanatory trial (see appendix 1).

Appendix 1:

Trial design characteristics

According the PRagmatic-Explanatory Continuum Indicator Summary (PRECIS2) criteria, the HLP design favours a pragmatic trial (figure 1). Figure 1 was created by reaching a consensus for each domain from four investigators on the study team using a 1 to 5 ordinal scale from explanatory to pragmatic.(60) (1) The eligibility criteria would allow for a broadly representative population. However, those who do not speak English and/ or had extreme mental health concerns be excluded. (2) Patients are recruited in primary care settings as well as through advertisements. (3). The trial is being conducted in a community based academic setting, however, there are similarities to a usual care setting. (4) Any provider familiar with the principles of cognitive behaviour therapy and health behaviour would be able to develop goals, action plans and conduct education sessions. However, specialized providers including a dietician are a part of the trial. (5) Delivery of educational sessions and goal setting is flexible, however, there are some restrictions based on participant and provider availability. (6) Participants have the choice to attend as little or as many sessions as they would like. (7) Participants enrolled in the MIP will be followed with more frequent visits and more extensive data collection than would occur during usual care routines. (8) The primary outcome of goal attainment is a clinically meaningful outcome to the study participants. (9) Due to the limited sample size of the pilot study there is no intention to treat analysis. Overall, most of the PRECIS-2 domains for the HLP pilot study were assessed to be pragmatic, though this appraisal is potentially biased since it was conducted by investigators associated with the study.(61)



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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5
	2b	Specific objectives or research questions for pilot trial	5-6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	9;13
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	13
	4b	Settings and locations where the data were collected	13
	4c	How participants were identified and consented	13
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-12
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	14
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	13
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	13
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	13

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	13
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	9-10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	7-8;16
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	13
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	16
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	17
	19a	If relevant, other important unintended consequences	17
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	N/A
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	N/A
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	N/A
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	N/A
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3
Protocol	24	Where the pilot trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18
	26	Ethical approval or approval by research review committee, confirmed with reference number	18

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Feasibility and implementation of a healthy lifestyles program in a community setting in Ontario, Canada: Protocol for a pragmatic mixed methods pilot study

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ABSTRACT

Introduction

Rates of chronic conditions, such as diabetes, cardiovascular disease, and obesity are increasing in Canada and internationally. There are effective lifestyle interventions that are known to improve chronic conditions. However, there is often a gap in "how to" make lifestyle changes. Mental health and other determinants of health play a role in the development and progression of chronic conditions. Changing habits takes time and requires the use of multiple techniques, including mental health and behavioural change strategies, based on a person's needs. A new, multidisciplinary, person-centered, and evidence- and practice-based program has been created to address these needs. This proposal aims to evaluate the feasibility and implementation of this program and to determine changes in participant-directed and clinical outcomes through a pilot study.

Methods and analysis

A pragmatic mixed methods design will be used to study multiple dimensions of the year-long healthy lifestyles program. The pilot study includes a randomized controlled trial, with 30 participants randomized to either the program or to a comparator arm, and qualitative components to determine the feasibility of the program, including recruitment and retention, data missing rates, and resources needed to run this program. Changes in participant-directed and clinical outcomes will be measured. Descriptive statistics, t-tests and repeated measures ANOVA for within group comparisons and generalized estimating equations (GEE) for between group analyses will be used. Qualitative interviews of program staff and healthcare providers and family focus groups will be used to further enhance the findings and improve the program.

Ethics and Dissemination

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. Informed consent will be obtained prior to enrolling any participant into the study. Participant IDs will be used during data collection and entry. Peer-reviewed publications and presentations will target researchers, health professionals, and stakeholders.

Trial registration ClinicalTrials.gov Identifier: NCT03258138
Hamilton Integrated Research Ethics Board (HiREB) project number: 3793

Keywords

Health services research, primary care, mental health, preventive medicine, patient-centred medicine

Strengths and limitations of this study

- Integration of quantitative and qualitative data are used to holistically evaluate the healthy lifestyles program.
- The study evaluates a complex intervention for behaviour change incorporating mental health strategies.
- It is a pragmatic study, which allows for a wider range of participants to be studied and increases the external validity of the results.
- The staff and participants are not blinded to the intervention.

INTRODUCTION

Chronic conditions, such as diabetes, cardiovascular disease, and obesity, are rising in Canada and internationally.[1-6] In addition, 1 out of every 3 Canadians meet the criteria for mental or substance use disorder at some point in their lives.[7] These chronic conditions can, on their own or as co-morbidities, impact the quantity and quality of people's lives.[4, 8-12] The link between mental and physical health is well-established in the literature.[10-12] People living with chronic conditions often have to adjust their expectations regarding their employment or lifestyle, which may have long-lasting effects on their mental health.[13]

Risk factors, including tobacco use, unhealthy diet and physical inactivity, are partially responsible for this rise in chronic diseases.[4, 14] Mental health is also affected by poor lifestyle habits.[14, 15] Many of these risk factors are modifiable, suggesting they are amenable to intervention. Lifestyle changes, including increasing physical activity, obtaining sufficient quality sleep, and the consumption of healthy foods, can reduce symptoms of physical and mental illnesses.[16-18] However, even if people know the benefits of having healthier habits, there is often a gap in "how to" make these changes.[19]

Setting goals can be integral in changing behavior and improving health.[20] Goals that center around behavioral changes, such as working out for thirty minutes every day, compared to physiological changes, such as losing five pounds, are advantageous, as they are under a person's direct control and can result in observable changes.[20] Individuals also exhibit greater commitment to behavioral changes when goals are personalized.[20] However, sometimes setting goals is insufficient to instigate behavioral changes.[21] Intention to achieve a goal does not equip an individual to deal with difficulties in self-regulation, in dealing with distractions and competing goals, or with over-extending oneself in goal striving.[22] Action plans can be used along with goal setting, as they outline the when, where and how the person will achieve their health goals. They also help individuals identify potential barriers and facilitators to goal achievement.[21]

Lifestyle programs that incorporate cognitive behavioural therapy (CBT) have been shown to help with weight loss, insomnia, anxiety and depression.[23-26] CBT is a type of psychotherapy that focuses on challenging dysfunctional or negative cognitions and beliefs and addressing maladaptive behaviours.[27] In addition, interventions designed with a theoretical foundation have been shown to be more successful than those without a theoretical base.[28] In particular, an ecological approach to behavior change allows for the inclusion and assessment of factors at the individual, interpersonal, institutional or community, and policy levels.[29] For example, determinants of health, such as income insecurity and inaccessible transportation, play a role in the development and progression of chronic conditions and can also act as barriers to achieving healthy lifestyles.

Changing habits takes time and requires the use of multiple techniques, such as those described above, based on a person's needs. Additionally, behavioural modification programs need to account for concurrent conditions and physical limitations. This type of person-centered care is a different approach than simply bringing more services to one location, or having services follow individuals.[30-32] This person-centered approach starts by attending to the needs of individuals, such as improving mood or finding motivation, within the context and limitations of their condition(s). The hypothesis is that approaching problems from the individual's perspective, and providing the tools, skills and supports to meet self-identified goals, will lead to more sustainable improvements in health-related quality of life, which can, in turn, lead to improvements in clinically-relevant indicators, such as lipid levels or smoking cessation.

This person-centered approach is not mainstream in the clinical setting and few individuals have access to behavioural therapists. Furthermore, many current available services and research studies address only one condition or patient population, exclude those who cannot participate in pre-set physical activity or exercise programs, focus only on secondary or tertiary prevention, or neglect the role of mental health or the determinants of health in lifestyle changes.[33-35] A new, multidisciplinary, person-centred, and evidence- and practice-based healthy lifestyles program has been created to address these needs.[36] This proposal aims to evaluate the feasibility and implementation of a healthy lifestyles program through a pilot study.

Novel intervention

Individuals will be enrolled in a healthy lifestyles program for one year. This amount of time will allow for determination of participant goals, identification of barriers and facilitators, healthy lifestyle education, and modification of individualized action plans. Participants will meet weekly with a health professional for an hour

for facilitated group health and wellness learning sessions or peer support sessions. The health and wellness learning sessions will provide a platform for concepts from a variety of health behaviour theories and CBT to be combined with evidence- and practice-based recommendations for healthy lifestyles.[23, 29, 36-38] These will provide the basis for the individualized action plans. Monthly individual sessions with a family physician trained in medical CBT, a dietician and a physical therapist will help individuals tailor their action plans to their particular circumstances and needs.[39, 40] The group sessions will allow for facilitated discussions where individuals explore barriers and facilitators to achieving their goals and will provide an interpersonal component to the program. Participants will also receive help in finding community programs to support healthy lifestyles.

A preliminary program manual has been developed. Education sessions include: S – Session; S1- Introduction to Program; S2 – Identifying health goals; S3 – Healthy mindsets and stress management; S4 – Creating a life compass; S5 – Building resources; S6 – Active lifestyles; S7 – Healthy eating; S8 – Identifying and overcoming barriers; S9 – Finding motivation; S10 – Living your values and addressing life changes and adversities; S11 – Advanced stress management techniques; S12 – The self within us; S13 – Building healthy relationships; S14 – Advanced time management techniques; S15 – Increasing self-efficacy; S16 - Increasing your social circle; S17 – Mental wellbeing and chronic pain; S18 – Revisiting goals and reflecting on self-growth. The first 8 sessions will be offered in consecutive weeks and the remaining sessions will be offered once a month interspersed with peer-support sessions. Changes in these topics will be possible based on participants' needs, and the program manual will be updated following this pilot study. A graduation ceremony will be provided for program participants and family/friends along with a certificate of completion for those who remain in the study.

Preliminary evidence to support this approach

Brief modified versions of these sessions have been used in presentations to graduate students on stress management, time management, and in classroom settings through a Theories of Health Behaviour course taught by the principal investigator at McMaster University. In addition, a pre-trial test run (Summer 2017) with nine volunteers enhanced the style of delivery, format and content of the first 8 health and wellness learning sessions and the initial assessment segments of the program. As a form of concept testing, feedback from the pre-trial sessions informed the content and structure of the program and reinforced the potential of the program to address gaps in current care. This was not published as no data was collected.

Comparator group

The literature highlights that there is no gold standard for developing a placebo control group in psychosocial research.[41, 42] In order to evaluate the specific parameters of the healthy lifestyles program that may influence its effectiveness, cost, duration, frequency and intensity, a comparator group that will set goals and action plans has been chosen.[41] Conducting a traditional sham or placebo control group for an entire year may not provide useful information around effectiveness and would use a considerable amount of resources. For this study, the comparator group will meet with a research assistant trained in theories of health behaviour every three months to develop personalized health goals and action plans. A certificate of completion will be provided for those who remain in the study.

Research question and study hypothesis

Does a year-long healthy lifestyles program, based on CBT and behavioural theories provided through group and individual sessions along with usual care, compared to development of health goals and action plans along with usual care help meet participant-directed and clinical outcomes for adults? We hypothesize that the healthy lifestyles program will be feasible and more effective for helping participants meet their health goals compared to simply setting goals and action plans.

Goals and objectives

The goal of this pilot project is to determine the feasibility and implementation of the healthy lifestyles program. This pilot study will also identify the conditions for a larger randomized controlled trial. Evaluating the context, including the site and materials used, of this pilot phase will help determine if, and how, the

program should be considered for scaling up in other parts of Canada and/or internationally. The comparator group will help determine if setting goals and an action plans are just as useful. See Table 1 for study objectives, analysis plan and outcomes.

Table 1. Study objectives, outcomes and analysis plans

Objectives		**Outcomes**	**Analysis**	**Hypothesis**
Primary				
Assess implementation and feasibility	Assess feasibility of recruitment, retention, group size and missing data	Recruitment and retention rates, attendance per session, missing data	Descriptive statistics	The healthy lifestyles program is feasible and acceptable
	Assess resources needed to run program	Health professionals needed, numbers and sizes of rooms needed for group and individual sessions, materials needed, costs and medical utilization logs	Descriptive statistics, cost analysis	
	Participant feedback	Participant satisfaction surveys	Descriptive statistics and thematic analysis for open-ended questions	
		Qualitative individual exit interviews	Thematic analysis	
	Staff feedback	Individual staff interviews	Thematic analysis	
	Family member feedback	Family focus groups	Thematic analysis	
	Healthcare provider feedback	Individual healthcare provider interviews	Thematic analysis	
Secondary				
Participant-directed outcomes	Assess the development of and progression of participant-directed goals	Goal development and measures	Changes within and between groups; Descriptive statistics, t-tests and repeated measures ANOVA for within group comparisons and generalized estimating equations (GEE) for between group analyses.	The intervention group will show greater movement in meeting goals
Clinical outcomes	Health-related quality of life, anxious and depressive symptoms, sleep, loneliness, stress, and other indicators (HbA1C, fasting lipids, and CBC as dictated by current guidelines), blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Staging System (if relevant)	Rate of completion and outcomes of scales and other measures		The intervention group will show greater improvement in these measures

METHODS AND ANALYSIS

Study design

This study will combine multiple designs (pilot study, pragmatic trial, mixed methods study), as previously reported by Samaan et al.[33] This will allow for the flexibility needed to study multiple dimensions of a new program, especially one designed for creating healthy lifestyles through the development of participant-directed goals and individualized action plans.[43-46] Elements of both concurrent and embedded mixed methods designs will allow for quantitative and qualitative data to be used to inform aspects of the program, while also allowing for different research questions to be asked that require different types of data that link up at multiple points of the study.[46] For example, the embedded design will allow for qualitative data to be collected to add depth to the quantitative empirical findings, to answer questions around the process of implementing the program, and to test and inform the program.[46]

This study will not be blinded as the amount of exposure to the program will be known to participants and providers. Research assistants will be in contact with participants, including for scheduling, so they will also not be blinded. It is pragmatic in that it will be conducted in a real-life setting with few criteria for exclusion, which allows for a wider range of participants to be studied and increases the generalizability of findings (see figure 1).[43] This study proposes a first stage that will examine the feasibility and implementation of the intervention. These findings will inform other stages of the study and the evaluation of a larger, scaled-up, intervention. For example, sample sizes will be determined for a randomized controlled trial based on effect sizes found through this pilot phase.

The qualitative components will include semi-structured exit interviews of remaining participants at 12 months, and program staff and participants' healthcare providers at 6 months and 12 months. In addition, focus groups will be conducted with family members of participants at 9 months. These elements will provide perspectives from multiple stakeholders for improving the healthy lifestyles program and on their roles in creating and maintaining healthy lifestyles. The pragmatic design was, in part, chosen to allow for the interviews and participant satisfaction surveys to be used to make changes to the program, or its delivery, while the study continues.

Patient and public involvement

People with chronic conditions were part of the pre-trial test run of the program and helped develop the protocol as collaborators. In addition, as a person-centered program, participants will be involved in the development of relevant personal goals and their scales. They will also provide feedback on the program throughout the study through participant surveys. This feedback will be used pragmatically to shape the program during the study, if needed, to fit participants' needs. Any changes made will be noted in the final report. All collaborators will be invited to review the results and determine implications of these findings for future practice and research.

Setting

This study will be conducted through McMaster University, and the site of the study will be at the David Braley Health Sciences Centre, Hamilton, Ontario. This site includes classrooms and offices to hold the group and individual sessions. It is accessible and centrally located in Hamilton.

Training of health professionals and research staff

The health professional leading the intervention is a licensed family physician with certification in medical CBT. The dietician and physical therapist are fully licensed through their respective professional associations. Research assistants will include students from a variety of undergraduate and graduate

programs at McMaster, and they will have training on research ethics and other aspects of data collection and analysis. Training will be provided on how to support participants in the comparator group to identify goals. Training will also be provided on how to conduct participant interviews and focus groups, and how to maintain field notes. Training will be carried out mainly by the principal investigator with additional support from the co-authors who have practice and research experience in these areas.

Sampling and recruitment

Participants in the randomized trial will include English-speaking individuals 18 years of age or older. Participants must be able to engage in the group sessions and understand and sign the informed consent form. Exclusion criteria will include people with unstable medical or mental health conditions as self-identified or identified through the recruitment process. Fifteen participants will be recruited for each arm of the randomized trial. This number accounts for ideal numbers of people involved in small group sessions based on practice experience and for potential attrition throughout the year while allowing for interpersonal interactions amongst participants.[23-26] Recruitment posters will be placed in local doctors' offices and in community settings, such as office buildings, coffee shops and grocery stores, after obtaining consent from the facilities. The posters will contain contact information for the research assistant and a link to a healthy lifestyles program website. The website will provide only information about the research study and how to contact the research assistant during the duration of the study. A Twitter account will be set up linked to the website to reach a broader audience, however, any information will only advertise the research study. In addition, advertisements will be placed in local media outlets, as needed.

The research assistant will obtain consent and enroll participants into the study. Healthcare professionals involved with routine participant care or with the conduct of the program will not be directly involved in enrolling participants into the study or obtaining informed consent. A participant maintains the right to drop out of the study at any time. However, the numbers and reasons for dropping out of the study will be sought and noted as part of the program evaluation. Recruitment will continue until the program starts, if needed.

Sampling and recruitment for qualitative components

All participants and program staff will partake in semi-structured interviews. If consent is given by participants to share information with their healthcare providers, healthcare providers involved in the participant's care outside of the study will be approached to participate in semi-structured interviews. Family focus groups will include family members, who are 16 years of age or older and English-speaking, of participants in either arm. Outreach to family members will occur through participants. Informed consent will be obtained prior to the interviews or focus groups.

Allocation and randomization

Each participant will be assigned a random number using the RAND function on Excel. Participants will be allocated to the healthy lifestyles program or to the comparator group in a ratio of 1:1, starting with the lowest number. If two participants are in a relationship, they will be placed in the same group based on who is randomized by the lowest number. A research assistant not involved in the recruitment or in the program will allocate the participants.

Data collection procedures

Paper-based and electronic measures will be used to collect data. See Table 2 for a list and description of instruments used in the pilot study. Paper charts, used only for the program or comparator group, will be reviewed when possible to gather data, such as participant goals and action plans. The rest of the data, such

as mental health scales, will be input directly by participants through the use of a tablet with an app for REDCap, a secure online research database. All other information, such as measurements, will otherwise be input by research team members into REDCap secure data storage using a study identifier. Access to REDCap is password protected and only team members will have access.

With the support of the program team or the research assistant for the comparator group, participants will identify relevant health goals and define how to measure these goals on a 1-7 scale, with 1 being the "worst case," 7 being the "best case," and 4 being the "middle." Therefore, measurements will also be participant-relevant while allowing for a variety of goals to be measured. This is a novel approach to goal development for healthy lifestyle changes as the endpoint is not a specific time but rather sustainable habit changes. This pilot study will allow the testing of this approach to goal development. In addition, scales for motivation, stages of change, and self-efficacy will be included for each goal.[47, 48, 49] For measuring motivation, the question will be asked, "How important is it to you to make this change?" and the scale will range from 1-'Do not want to make this change at all' to 7-'Very much want to make this change and I am willing to work hard for it.' A modified stages of change [48] scale will be measured by asking "Have you ever tried to make this change?" Precontemplation, where a person has not thought about making a behaviour change, will be assessed as 1-'I have never thought about making this change before, and I am not ready to try.' Contemplation, where a person is weighing the pros and cons of making a change, will be assessed as 2-'I have thought about making this change but have never tried." Planning is where a person is preparing for gathering resources to make a change, which will be measured as 3-'I have thought about making this change and have started planning how to do it, but I am not doing it yet." Action is the stage where a behaviour has started and will be measured as either 4-'I have made some changes within the past 6 months but I find it hard to keep up' or 5-'I have made some changes within the past 6 months and I find it easy to do.' Maintenance is the stage where a person has been making changes for at least 6 months and relapse is considered less common as the change is considered a habit. This stage will be measured as 6-'I have made changes for more than 6 months.' Lastly, a measure was added for relapse, or reverting back to an old habit, as 7-'I used to do this consistently for some time, but I stopped.' Self-efficacy, which is the belief people have in their ability to perform a task or behaviour,[49] will be evaluated by asking, "How confident are you that you could make this change if you wanted to?" A scale will be used ranging from 1-'I do not feel I would be able to make this change' to 7-'I feel very confident I could make this change now."

If labwork information is not available, participants will be asked to visit their family physician for a requisition for labwork to be drawn, if they meet current screening guidelines. For HbA1C and lipids, this includes being 40 years of age or older or having risk factors as outlined in the Canadian guidelines for diabetes and cardiovascular disease, respectively.[50, 51] A complete blood count (CBC) will only be conducted if the participant has symptoms, such as fatigue, or a history of cancer, infections or blood disorders as determined by the clinicians involved in the study or by the participant's family physician. Measurements will include blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, and Edmonton Obesity Staging System (if relevant).[52]

Participant satisfaction and feedback will be assessed through surveys developed for this study at 3, 6 and 9 months. A weekly nutrition journal and physical activity journal and a costs and medical utilization log will be provided to participants and collected once every three months. Worksheets for each health and wellness learning session will be provided for participants in the intervention group only, which will not be collected for study purposes. These instruments will all be tested and modified, if needed, through this pilot study.

For research purposes, the pilot will involve the use of a number of measures of health status and health-related quality of life. The routine application of the intervention would involve a more parsimonious set of measures, based on findings through this study. Validated health and wellbeing scales will be filled out

by participants at baseline and every three months to assess change in these indicators (five times total). The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) will only be filled out at baseline to ensure goals related to physical activity are appropriate given a participant's health status. The remainder of these scales were selected for addressing a holistic range of mental health indicators that are dealt with in the healthy lifestyles program. The RAND SF-36 [53, 54] and Health Utilities Index (HUI) 2/3 [55-57] are validated instruments for health-related quality of life. The decision to use both is to compare findings from these instruments. The Patient Health Questionnaire (PHQ) is made up of five domains to evaluate for depression (PHQ-9), anxiety (GAD-7), bulimia, somatoform disorders and alcohol misuse.[58-60] The Insomnia Severity Index (ISI) identifies insomnia symptoms.[61] The Life Change Index Scale, otherwise known as the Holmes and Rahe stress scale, has been found to correlate with medical utilization in a family practice setting.[62] In addition, the Perceived Stress Scale (PSS) measures the degree to which situations in one's life are perceived as stressful.[63, 64] Lastly, the DeJong Gierveld 6-item Loneliness Scale captures both emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network).[65, 66]

Administrative data will be used for adherence information (e.g., number of participants attending each education session) and for data on costs of running the program (see Table 1).

Qualitative data collection

Interviews and focus groups will be recorded with a digital recorder and transcribed. Field notes will be taken during these interviews and focus groups to describe the setting and keep track of other events.

Data will be entered into the relevant software (Excel, SPSS, Microsoft Word) by research assistants. All information will be kept confidential and participants IDs will be used whenever data is coded. De-identified data will be extracted for analysis.

Table 2. Pilot study instruments

Instrument	**Purpose**	**Administered**	**Time to complete (min)**	**Timepoints Intervention**	**Timepoints Comparator**
Enrollment form	To obtain contact information and preferences, emergency contact information, and sharing of information with primary care provider	Self	5	Baseline	Baseline
Data collection form	Baseline data and to measure changes over time on participant characteristics (including demographics), health conditions, and health habits	Self	10 5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo, 12mo
Physical activity journal	To track usual physical activity over a week and over time	Self	10/ week	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Nutrition journal	To track usual eating content and habits over a week and over time	Self	10/week	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Health and wellness learning session worksheets	To reflect on personal habits and reasons for change	Self	5-30/week	In health and wellness learning sessions and for reflection between sessions	

Goals, action plan and barrier identification	To develop personalized plan for sustainable lifestyle changes and to identify barriers	Team members and participants	Initial 45-60; Follow-up 10-15	Monthly in individual sessions	Baseline, 3mo, 6mo, 9mo,12mo
Physical Activity Readiness Questionnaire for Everyone PAR-Q+	Physical activity readiness	Self	3	Baseline	Baseline
SF-36, Health Utilities Index (HUI)2/3	Quality of life	Self	5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Patient Health Questionnaire (PHQ)	Baseline and change over time for depression and anxiety	Self	5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Insomnia Severity Index (ISI)	Baseline and change over time of insomnia	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Perceived stress scale	Baseline and change over time of perceived stress	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Life Change Index Scale	Baseline and change over time of stressors	Self	3	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
DeJong Gierveld Loneliness Scale	Baseline and change over time for loneliness	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Participant satisfaction surveys	To measure participant satisfaction and improve program	Self	10	3mo, 6mo, 9mo	3mo, 6mo, 9mo
Costs and medical utilization log	To measure direct costs and medical utilization	Self	Variable	Continuous	Continuous

Data analysis

Quantitative

See Table 1 for a description of the objectives of the study, outcomes measured, and analytic techniques for each component. Quantitative data will be reviewed for missing data and entered into Excel and/or SPSS. Descriptive statistics will be presented for the participants in the study. Changes within groups over time will be assessed with t-tests, for specific time points, and repeated measures ANOVA, and differences between groups will be assessed using generalized estimating equations (GEE). Since this is a pilot study, this information will be looked at to help inform a larger randomized trial. Total costs for the program will be recorded through administrative data, and cost-effectiveness analyses will be conducted to the extent possible using data provided by participants on the costs and medical utilization logs. This pilot study will allow testing of the costs and medical utilization log instrument.

Qualitative

Transcripts, field notes, and documents will be coded using Microsoft Word. Concepts and themes will be developed using a constant comparative method of analysis in which new information is compared to previous information. Themes related to the concept of the program, implementation of the program and feasibility will be developed, among others. Confirming and disconfirming evidence will be sought to ensure data saturation or completeness of the findings.[67]

Data and participant monitoring

Team members will meet weekly to discuss study progress and review data quality and monitoring of attendance or any concerns raised by participants or clinicians.

Participants will fill out mental health scales, which will be scored during data collection in REDCap. Research assistants will have training on interpreting these scales. If any concerns around these findings or other signs of deterioration are encountered by anyone on the research or program teams, the principal investigator or alternate clinician will be notified while the participant is still in contact with the team member. An assessment will be conducted, and if any concerns arise for self harm or harm to others, proper guidelines will be followed, including creating a safety plan, contacting the participant's family physician and/or providing more frequent follow-ups, or contacting emergency services, as deemed appropriate.[68]

Few risks are anticipated for this study. However, there could be anxiety or fatigue caused by participating in the study or in filling out the forms. If any concerns are noted, the principal investigator will attend to these concerns and may remove the participant from the study, following a discussion with the participant and the team, if this is deemed in the participant's best interests. This study does not require a data and safety monitoring board since there are no drugs or devices being tested and is considered low risk.

ETHICS AND DISSEMINATION

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. If any changes are made to the research design, HiREB will be notified and changes will be made based on their recommendations. A research assistant will explain the nature of the study to potential participants, their rights as participants, confidentiality of their data, voluntary entry into the study, and their ability to withdraw from the study at any time.[69, 70] There is minimal risk of entering this study, however, participants will be informed about the potential risks of unintended disclosure, where they may potentially give away information about themselves or about a third party during qualitative exit interviews which could lead to recognition of themselves or the third party (in which case confidentiality will be sought for the third party as well). In addition, there are some risks to starting or increasing any exercise activity, such as injury. However, the benefits of increasing mobility outweigh most of the risks of potential injury and having trained team members and setting realistic goals will allow for gradual adjustments in their mobility levels. Any questions will be answered, and informed consent will be obtained prior to enrolling any participant into the study. All data gathered for the study will be kept confidential by using identifiers (with identifiers and identifying data kept separately), and access will only be given to the research team members. Paper documents will be stored in a locked cabinet. Electronic documents will be kept on password-protected computers. All data will be input into REDCap, which requires a password and tracks users. Participants will have the option to provide consent for sharing of information with their primary care or other treating physician(s). No information will be released without the participant's consent, unless ordered through a court or in the case of harm to self or others, where participant information may need to be released for emergency treatment. This information is stated in the informed consent form. In the case of a data breach, the privacy officer will be contacted as soon as the breach is detected and McMaster University protocols will be followed.

Participants in both arms will receive a modest monetary compensation of $30 each time they meet with the research assistant for data collection every three months for an expected time of 1 hour (5 times total). This amount is seen as a token of appreciation yet non-coercive. Comparator-arm participants will also be allowed to participate in the healthy lifestyles program at a later date on the condition that the program is still running.

Timeline and activities and knowledge translation

The pilot phase will take approximately 24 months (beginning in April 2018 and ending in April 2020), which includes time for recruiting participants, planning logistics, running the full program, analyzing data, and generating knowledge translation activities. Knowledge exchange will include feedback from participants, staff, health providers and family members. Peer-reviewed publications and presentations at conferences (e.g., family medicine, public health) will target researchers and health professionals. Policymakers and other stakeholders will be engaged to identify needs and any policy implications of the findings.

Post-trial care

Participants will continue to receive usual care from their primary care physicians during and after the study.

DISCUSSION

This pilot phase will assess the feasibility and implementation of a healthy lifestyles program. In the longer-term, findings of this and future research in this area are expected to address gaps in knowledge around individuals' attainment of healthier lifestyles, on health services organization, and on community and policy efforts to support these changes. The impact on participant experiences and outcomes is one of the main objectives of this study. The healthy lifestyles program is person-centered in that it allows for participants to self-identify relevant health goals and to develop realistic and sustainable action plans to achieve their goals. The purpose of evaluating the healthy lifestyles program is to understand if and how it works, to iteratively improve the program, and to understand the implementation process so that it can be scaled up successfully in other sites.

List of abbreviations

BMI – Body mass index

CBC – Complete blood count

CBT – Cognitive behavioural therapy

EOSS - Edmonton Obesity Staging System

GEE - Generalized estimating equations

HiREB – Hamilton Integrated Research Ethics Board

HUI – Health Utilities Index

ISI – Insomnia Severity Index

PAR-Q+ - Physical Activity Readiness Questionnaire for Everyone

PHQ – Patient Health Questionnaire

RAND SF36 – 36-Item Short Form Survey

Declarations

Ethics approval and consent to participate

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. Project number: 3793

Competing interest

D.F. has a proprietary interest in Health Utilities Incorporated, Dundas, ON, Canada. HUI Inc. distributes copyrighted Health Utilities Index (HUI) materials and provides methodological advice on the use of the HUI. The other authors declare no conflict of interest.

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Author's contributions

EA developed the research question and protocol. EA and MQ drafted the manuscript. JS, AS and EA revised the manuscript. EA, MQ, LM, JL, CL, MW, ZS and DF contributed to the design of the protocol. JF contributed to the conceptual design of the work. All authors read and approved the final manuscript.

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Figure 1 Legend:

Figure 1. PRECIS-2 wheel for the healthy lifestyles program pilot trial design. This figure was created by reaching a consensus for each domain from four investigators on the study team using a 1 to 5 ordinal scale from explanatory (blue line towards the centre) to pragmatic (blue line towards the periphery).[71] Aside from the *organization* domain, the PRECIS-2 wheel illustrates that the study design is closer to a pragmatic than an explanatory trial (see appendix 1).

Appendix 1:

Trial design characteristics

According to the PRagmatic-Explanatory Continuum Indicator Summary (PRECIS2) criteria, the HLP design favours a pragmatic trial (figure 1). Figure 1 was created by reaching a consensus for each domain from four investigators on the study team using a 1 to 5 ordinal scale from explanatory to pragmatic.[71] (1) The eligibility criteria allows for a broadly representative population. However, those who do not speak English and/ or have unstable physical or mental health concerns will be excluded. (2) Participants will be recruited from the community. (3). The trial is being conducted in a community based setting. (4) Any physician or advanced practice healthcare provider familiar with the principles of cognitive behaviour therapy and health behaviour would be able to develop goals, action plans and conduct education sessions. However, specialized providers including a dietician will be part of the trial. (5) Delivery of educational sessions and goal setting will be flexible, however, there will be some restrictions based on participant and provider availability. (6) Participants will have the choice to attend as few or as many sessions as they would like. (7) Participants enrolled in the healthy lifestyles program will be followed with more frequent visits and more extensive data collection than would occur during usual care routines. (8) The primary outcome of goal attainment will be a meaningful outcome to the study participants. (9) Due to the small sample size of the pilot study there will be no intention to treat analysis. Overall, most of the PRECIS-2 domains for the pilot study were assessed to be pragmatic, though this appraisal is potentially biased since it was conducted by investigators associated with the study.[72]

90x90mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___2_____
	2b	All items from the World Health Organization Trial Registration Data Set	___N/A_____
Protocol version	3	Date and version identifier	File name
Funding	4	Sources and types of financial, material, and other support	___15_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Cover and pg. 15
	5b	Name and contact information for the trial sponsor	Author – cover pg
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___15_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___13_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	6 and Table 1
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9 and Appendix 1
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	5-6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9 and 13

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__9-11, 13_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Table 1 and pg. 12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___13_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___8_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___13_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___N/A_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___13_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___13_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___13_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___15_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Informed consent
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___14_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	____14_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	Standard authorship guidelines will be used – not reported
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Protocol on ClinicalTrials.gov, others N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Informed consent forms, not included

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	__N.A_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Feasibility and implementation of a healthy lifestyles program in a community setting in Ontario, Canada: Protocol for a pragmatic mixed methods pilot study

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ABSTRACT

Introduction

Rates of chronic conditions, such as diabetes, cardiovascular disease, and obesity are increasing in Canada and internationally. There are effective lifestyle interventions that are known to improve chronic conditions. However, there is often a gap in "how to" make lifestyle changes. Mental health and other determinants of health play a role in the development and progression of chronic conditions. Changing habits takes time and requires the use of multiple techniques, including mental health and behavioural change strategies, based on a person's needs. A new, multidisciplinary, person-centered, and evidence- and practice-based program has been created to address these needs. This proposal aims to evaluate the feasibility and implementation of this program and to determine changes in participant-directed and clinical outcomes through a pilot study.

Methods and analysis

A pragmatic mixed methods design will be used to study multiple dimensions of the year-long healthy lifestyles program. The pilot study includes a randomized controlled trial, with 30 participants randomized to either the program or to a comparator arm, and qualitative components to determine the feasibility of the program, including recruitment and retention, data missing rates, and resources needed to run this program. Changes in participant-directed and clinical outcomes will be measured. Descriptive statistics, t-tests and repeated measures ANOVA for within group comparisons and generalized estimating equations (GEE) for between group analyses will be used. Qualitative interviews of program staff and healthcare providers and family focus groups will be used to further enhance the findings and improve the program.

Ethics and Dissemination

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. Informed consent will be obtained prior to enrolling any participant into the study. Participant IDs will be used during data collection and entry. Peer-reviewed publications and presentations will target researchers, health professionals, and stakeholders.

Trial registration ClinicalTrials.gov Identifier: NCT03258138
Hamilton Integrated Research Ethics Board (HiREB) project number: 3793

Keywords

Health services research, primary care, mental health, preventive medicine, patient-centred medicine

Strengths and limitations of this study

- Integration of quantitative and qualitative data are used to holistically evaluate the healthy lifestyles program.
- The study evaluates a complex intervention for behaviour change incorporating mental health strategies.
- It is a pragmatic study, which allows for a wider range of participants to be studied and increases the external validity of the results.
- The staff and participants are not blinded to the intervention.

INTRODUCTION

Chronic conditions, such as diabetes, cardiovascular disease, and obesity, are rising in Canada and internationally.[1-6] In addition, 1 out of every 3 Canadians meet the criteria for mental or substance use disorder at some point in their lives.[7] These chronic conditions can, on their own or as co-morbidities, impact the quantity and quality of people's lives.[4, 8-12] The link between mental and physical health is well-established in the literature.[10-12] People living with chronic conditions often have to adjust their expectations regarding their employment or lifestyle, which may have long-lasting effects on their mental health.[13]

Risk factors, including tobacco use, unhealthy diet and physical inactivity, are partially responsible for this rise in chronic diseases.[4, 14] Mental health is also affected by poor lifestyle habits.[14, 15] Many of these risk factors are modifiable, suggesting they are amenable to intervention. Lifestyle changes, including increasing physical activity, obtaining sufficient quality sleep, and the consumption of healthy foods, can reduce symptoms of physical and mental illnesses.[16-18] However, even if people know the benefits of having healthier habits, there is often a gap in "how to" make these changes.[19]

Setting goals can be integral in changing behavior and improving health.[20] Goals that center around behavioral changes, such as working out for thirty minutes every day, compared to physiological changes, such as losing five pounds, are advantageous, as they are under a person's direct control and can result in observable changes.[20] Individuals also exhibit greater commitment to behavioral changes when goals are personalized.[20] However, sometimes setting goals is insufficient to instigate behavioral changes.[21] Intention to achieve a goal does not equip an individual to deal with difficulties in self-regulation, in dealing with distractions and competing goals, or with over-extending oneself in goal striving.[22] Action plans can be used along with goal setting, as they outline the when, where and how the person will achieve their health goals. They also help individuals identify potential barriers and facilitators to goal achievement.[21]

Lifestyle programs that incorporate cognitive behavioural therapy (CBT) have been shown to help with weight loss, insomnia, anxiety and depression.[23-26] CBT is a type of psychotherapy that focuses on challenging dysfunctional or negative cognitions and beliefs and addressing maladaptive behaviours.[27] In addition, interventions designed with a theoretical foundation have been shown to be more successful than those without a theoretical base.[28] In particular, an ecological approach to behavior change allows for the inclusion and assessment of factors at the individual, interpersonal, institutional or community, and policy levels.[29] For example, determinants of health, such as income insecurity and inaccessible transportation, play a role in the development and progression of chronic conditions and can also act as barriers to achieving healthy lifestyles.

Changing habits takes time and requires the use of multiple techniques, such as those described above, based on a person's needs. Additionally, behavioural modification programs need to account for concurrent conditions and physical limitations. This type of person-centered care is a different approach than simply bringing more services to one location, or having services follow individuals.[30-32] This person-centered approach starts by attending to the needs of individuals, such as improving mood or finding motivation, within the context and limitations of their condition(s). The hypothesis is that approaching problems from the individual's perspective, and providing the tools, skills and supports to meet self-identified goals, will lead to more sustainable improvements in health-related quality of life, which can, in turn, lead to improvements in clinically-relevant indicators, such as lipid levels or smoking cessation.

This person-centered approach is not mainstream in the clinical setting and few individuals have access to behavioural therapists. Furthermore, many current available services and research studies address only one condition or patient population, exclude those who cannot participate in pre-set physical activity or exercise programs, focus only on secondary or tertiary prevention, or neglect the role of mental health or the determinants of health in lifestyle changes.[33-35] A new, multidisciplinary, person-centred, and evidence- and practice-based healthy lifestyles program has been created to address these needs.[36] This proposal aims to evaluate the feasibility and implementation of a healthy lifestyles program through a pilot study.

Novel intervention

Individuals will be enrolled in a healthy lifestyles program for one year. This amount of time will allow for determination of participant goals, identification of barriers and facilitators, healthy lifestyle education, and modification of individualized action plans. Participants will meet weekly with a health professional for an hour

for facilitated group health and wellness learning sessions or peer support sessions. The health and wellness learning sessions will provide a platform for concepts from a variety of health behaviour theories and CBT to be combined with evidence- and practice-based recommendations for healthy lifestyles.[23, 29, 36-38] These will provide the basis for the individualized action plans. Monthly individual sessions with a family physician trained in medical CBT, a dietician and a physical therapist will help individuals tailor their action plans to their particular circumstances and needs.[39, 40] The group sessions will allow for facilitated discussions where individuals explore barriers and facilitators to achieving their goals and will provide an interpersonal component to the program. Participants will also receive help in finding community programs to support healthy lifestyles.

A preliminary program manual has been developed. Education sessions include: S – Session; S1- Introduction to Program; S2 – Identifying health goals; S3 – Healthy mindsets and stress management; S4 – Creating a life compass; S5 – Building resources; S6 – Active lifestyles; S7 – Healthy eating; S8 – Identifying and overcoming barriers; S9 – Finding motivation; S10 – Living your values and addressing life changes and adversities; S11 – Advanced stress management techniques; S12 – The self within us; S13 – Building healthy relationships; S14 – Advanced time management techniques; S15 – Increasing self-efficacy; S16 - Increasing your social circle; S17 – Mental wellbeing and chronic pain; S18 – Revisiting goals and reflecting on self-growth. The first 8 sessions will be offered in consecutive weeks and the remaining sessions will be offered once a month interspersed with peer-support sessions. Changes in these topics will be possible based on participants' needs, and the program manual will be updated following this pilot study. A graduation ceremony will be provided for program participants and family/friends along with a certificate of completion for those who remain in the study.

Preliminary evidence to support this approach

Brief modified versions of these sessions have been used in presentations to graduate students on stress management, time management, and in classroom settings through a Theories of Health Behaviour course taught by the principal investigator at McMaster University. In addition, a pre-trial test run (Summer 2017) with nine volunteers enhanced the style of delivery, format and content of the first 8 health and wellness learning sessions and the initial assessment segments of the program. As a form of concept testing, feedback from the pre-trial sessions informed the content and structure of the program and reinforced the potential of the program to address gaps in current care. This was not published as no data was collected.

Comparator group

The literature highlights that there is no gold standard for developing a placebo control group in psychosocial research.[41, 42] In order to evaluate the specific parameters of the healthy lifestyles program that may influence its effectiveness, cost, duration, frequency and intensity, a comparator group that will set goals and action plans has been chosen.[41] Conducting a traditional sham or placebo control group for an entire year may not provide useful information around effectiveness and would use a considerable amount of resources. For this study, the comparator group will meet with a research assistant trained in theories of health behaviour every three months to develop personalized health goals and action plans. A certificate of completion will be provided for those who remain in the study.

Research question and study hypothesis

Does a year-long healthy lifestyles program, based on CBT and behavioural theories provided through group and individual sessions along with usual care, compared to development of health goals and action plans along with usual care help meet participant-directed and clinical outcomes for adults? We hypothesize that the healthy lifestyles program will be feasible and more effective for helping participants meet their health goals compared to simply setting goals and action plans.

Goals and objectives

The goal of this pilot project is to determine the feasibility and implementation of the healthy lifestyles program. This pilot study will also identify the conditions for a larger randomized controlled trial. Evaluating the context, including the site and materials used, of this pilot phase will help determine if, and how, the

program should be considered for scaling up in other parts of Canada and/or internationally. The comparator group will help determine if setting goals and an action plans are just as useful. See Table 1 for study objectives, analysis plan and outcomes.

Table 1. Study objectives, outcomes and analysis plans

Objectives		**Outcomes**	**Analysis**	**Hypothesis**
Primary				
Assess implementation and feasibility	Assess feasibility of recruitment, retention, group size and missing data	Recruitment and retention rates, attendance per session, missing data	Descriptive statistics	The healthy lifestyles program is feasible and acceptable
	Assess resources needed to run program	Health professionals needed, numbers and sizes of rooms needed for group and individual sessions, materials needed, costs and medical utilization logs	Descriptive statistics, cost analysis	
	Participant feedback	Participant satisfaction surveys	Descriptive statistics and thematic analysis for open-ended questions	
		Qualitative individual exit interviews	Thematic analysis	
	Staff feedback	Individual staff interviews	Thematic analysis	
	Family member feedback	Family focus groups	Thematic analysis	
	Healthcare provider feedback	Individual healthcare provider interviews	Thematic analysis	
Secondary				
Participant-directed outcomes	Assess the development of and progression of participant-directed goals	Goal development and measures	Changes within and between groups; Descriptive statistics, t-tests and repeated measures ANOVA for within group comparisons and generalized estimating equations (GEE) for between group analyses.	The intervention group will show greater movement in meeting goals
Clinical outcomes	Health-related quality of life, anxious and depressive symptoms, sleep, loneliness, stress, and other indicators (HbA1C, fasting lipids, and CBC as dictated by current guidelines), blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Staging System (if relevant)	Rate of completion and outcomes of scales and other measures		The intervention group will show greater improvement in these measures

METHODS AND ANALYSIS

Study design

This study will combine multiple designs (pilot study, pragmatic trial, mixed methods study), as previously reported by Samaan et al.[33] This will allow for the flexibility needed to study multiple dimensions of a new program, especially one designed for creating healthy lifestyles through the development of participant-directed goals and individualized action plans.[43-46] Elements of both concurrent and embedded mixed methods designs will allow for quantitative and qualitative data to be used to inform aspects of the program, while also allowing for different research questions to be asked that require different types of data that link up at multiple points of the study.[46] For example, the embedded design will allow for qualitative data to be collected to add depth to the quantitative empirical findings, to answer questions around the process of implementing the program, and to test and inform the program.[46]

This study will not be blinded as the amount of exposure to the program will be known to participants and providers. Research assistants will be in contact with participants, including for scheduling, so they will also not be blinded. It is pragmatic in that it will be conducted in a real-life setting with few criteria for exclusion, which allows for a wider range of participants to be studied and increases the generalizability of findings (see figure 1).[43] This study proposes a first stage that will examine the feasibility and implementation of the intervention. These findings will inform other stages of the study and the evaluation of a larger, scaled-up, intervention. For example, sample sizes will be determined for a randomized controlled trial based on effect sizes found through this pilot phase.

The qualitative components will include semi-structured exit interviews of remaining participants at 12 months, and program staff and participants' healthcare providers at 6 months and 12 months. In addition, focus groups will be conducted with family members of participants at 9 months. These elements will provide perspectives from multiple stakeholders for improving the healthy lifestyles program and on their roles in creating and maintaining healthy lifestyles. The pragmatic design was, in part, chosen to allow for the interviews and participant satisfaction surveys to be used to make changes to the program, or its delivery, while the study continues.

Patient and public involvement

People with chronic conditions were part of the pre-trial test run of the program and helped develop the protocol as collaborators. In addition, as a person-centered program, participants will be involved in the development of relevant personal goals and their scales. They will also provide feedback on the program throughout the study through participant surveys. This feedback will be used pragmatically to shape the program during the study, if needed, to fit participants' needs. Any changes made will be noted in the final report. All collaborators will be invited to review the results and determine implications of these findings for future practice and research.

Setting

This study will be conducted through McMaster University, and the site of the study will be at the David Braley Health Sciences Centre, Hamilton, Ontario. This site includes classrooms and offices to hold the group and individual sessions. It is accessible and centrally located in Hamilton.

Training of health professionals and research staff

The health professional leading the intervention is a licensed family physician with certification in medical CBT. The dietician and physical therapist are fully licensed through their respective professional associations. Research assistants will include students from a variety of undergraduate and graduate

programs at McMaster, and they will have training on research ethics and other aspects of data collection and analysis. Training will be provided on how to support participants in the comparator group to identify goals. Training will also be provided on how to conduct participant interviews and focus groups, and how to maintain field notes. Training will be carried out mainly by the principal investigator with additional support from the co-authors who have practice and research experience in these areas.

Sampling and recruitment

Participants in the randomized trial will include English-speaking individuals 18 years of age or older. Participants must be able to engage in the group sessions and understand and sign the informed consent form. Exclusion criteria will include people with unstable medical or mental health conditions as self-identified or identified through the recruitment process. Fifteen participants will be recruited for each arm of the randomized trial. This number accounts for ideal numbers of people involved in small group sessions based on practice experience and for potential attrition throughout the year while allowing for interpersonal interactions amongst participants.[23-26] Recruitment posters will be placed in local doctors' offices and in community settings, such as office buildings, coffee shops and grocery stores, after obtaining consent from the facilities. The posters will contain contact information for the research assistant and a link to a healthy lifestyles program website. The website will provide only information about the research study and how to contact the research assistant during the duration of the study. A Twitter account will be set up linked to the website to reach a broader audience, however, any information will only advertise the research study. In addition, advertisements will be placed in local media outlets, as needed.

The research assistant will obtain consent and enroll participants into the study. Healthcare professionals involved with routine participant care or with the conduct of the program will not be directly involved in enrolling participants into the study or obtaining informed consent. A participant maintains the right to drop out of the study at any time. However, the numbers and reasons for dropping out of the study will be sought and noted as part of the program evaluation. Recruitment will continue until the program starts, if needed.

Sampling and recruitment for qualitative components

All participants and program staff will partake in semi-structured interviews. If consent is given by participants to share information with their healthcare providers, healthcare providers involved in the participant's care outside of the study will be approached to participate in semi-structured interviews. Family focus groups will include family members, who are 16 years of age or older and English-speaking, of participants in either arm. Outreach to family members will occur through participants. Informed consent will be obtained prior to the interviews or focus groups.

Allocation and randomization

Each participant will be assigned a random number using the RAND function on Excel. Participants will be allocated to the healthy lifestyles program or to the comparator group in a ratio of 1:1, starting with the lowest number. If two participants are in a relationship, they will be placed in the same group based on who is randomized by the lowest number. A research assistant not involved in the recruitment or in the program will allocate the participants.

Data collection procedures

Paper-based and electronic measures will be used to collect data. See Table 2 for a list and description of instruments used in the pilot study. Paper charts, used only for the program or comparator group, will be reviewed when possible to gather data, such as participant goals and action plans. The rest of the data, such

as mental health scales, will be input directly by participants through the use of a tablet with an app for REDCap, a secure online research database. All other information, such as measurements, will otherwise be input by research team members into REDCap secure data storage using a study identifier. Access to REDCap is password protected and only team members will have access.

With the support of the program team or the research assistant for the comparator group, participants will identify relevant health goals and define how to measure these goals on a 1-7 scale, with 1 being the "worst case," 7 being the "best case," and 4 being the "middle." Therefore, measurements will also be participant-relevant while allowing for a variety of goals to be measured. This is a novel approach to goal development for healthy lifestyle changes as the endpoint is not a specific time but rather sustainable habit changes. This pilot study will allow the testing of this approach to goal development. In addition, scales for motivation, stages of change, and self-efficacy will be included for each goal.[47, 48, 49] For measuring motivation, the question will be asked, "How important is it to you to make this change?" and the scale will range from 1-'Do not want to make this change at all' to 7-'Very much want to make this change and I am willing to work hard for it.' A modified stages of change [48] scale will be measured by asking "Have you ever tried to make this change?" Precontemplation, where a person has not thought about making a behaviour change, will be assessed as 1-'I have never thought about making this change before, and I am not ready to try.' Contemplation, where a person is weighing the pros and cons of making a change, will be assessed as 2-'I have thought about making this change but have never tried." Planning is where a person is preparing for gathering resources to make a change, which will be measured as 3-'I have thought about making this change and have started planning how to do it, but I am not doing it yet." Action is the stage where a behaviour has started and will be measured as either 4-'I have made some changes within the past 6 months but I find it hard to keep up' or 5-'I have made some changes within the past 6 months and I find it easy to do.' Maintenance is the stage where a person has been making changes for at least 6 months and relapse is considered less common as the change is considered a habit. This stage will be measured as 6-'I have made changes for more than 6 months.' Lastly, a measure was added for relapse, or reverting back to an old habit, as 7-'I used to do this consistently for some time, but I stopped.' Self-efficacy, which is the belief people have in their ability to perform a task or behaviour,[49] will be evaluated by asking, "How confident are you that you could make this change if you wanted to?" A scale will be used ranging from 1-'I do not feel I would be able to make this change' to 7-'I feel very confident I could make this change now."

If labwork information is not available, participants will be asked to visit their family physician for a requisition for labwork to be drawn, if they meet current screening guidelines. For HbA1C and lipids, this includes being 40 years of age or older or having risk factors as outlined in the Canadian guidelines for diabetes and cardiovascular disease, respectively.[50, 51] A complete blood count (CBC) will only be conducted if the participant has symptoms, such as fatigue, or a history of cancer, infections or blood disorders as determined by the clinicians involved in the study or by the participant's family physician. Measurements will include blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, and Edmonton Obesity Staging System (if relevant).[52]

Participant satisfaction and feedback will be assessed through surveys developed for this study at 3, 6 and 9 months. A weekly nutrition journal and physical activity journal and a costs and medical utilization log will be provided to participants and collected once every three months. Worksheets for each health and wellness learning session will be provided for participants in the intervention group only, which will not be collected for study purposes. These instruments will all be tested and modified, if needed, through this pilot study.

For research purposes, the pilot will involve the use of a number of measures of health status and health-related quality of life. The routine application of the intervention would involve a more parsimonious set of measures, based on findings through this study. Validated health and wellbeing scales will be filled out

by participants at baseline and every three months to assess change in these indicators (five times total). The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) will only be filled out at baseline to ensure goals related to physical activity are appropriate given a participant's health status. The remainder of these scales were selected for addressing a holistic range of mental health indicators that are dealt with in the healthy lifestyles program. The RAND SF-36 [53, 54] and Health Utilities Index (HUI) 2/3 [55-57] are validated instruments for health-related quality of life. The decision to use both is to compare findings from these instruments. The Patient Health Questionnaire (PHQ) is made up of five domains to evaluate for depression (PHQ-9), anxiety (GAD-7), bulimia, somatoform disorders and alcohol misuse.[58-60] The Insomnia Severity Index (ISI) identifies insomnia symptoms.[61] The Life Change Index Scale, otherwise known as the Holmes and Rahe stress scale, has been found to correlate with medical utilization in a family practice setting.[62] In addition, the Perceived Stress Scale (PSS) measures the degree to which situations in one's life are perceived as stressful.[63, 64] Lastly, the DeJong Gierveld 6-item Loneliness Scale captures both emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network).[65, 66]

Administrative data will be used for adherence information (e.g., number of participants attending each education session) and for data on costs of running the program (see Table 1).

Qualitative data collection

Interviews and focus groups will be recorded with a digital recorder and transcribed. Field notes will be taken during these interviews and focus groups to describe the setting and keep track of other events.

Data will be entered into the relevant software (Excel, SPSS, Microsoft Word) by research assistants. All information will be kept confidential and participants IDs will be used whenever data is coded. De-identified data will be extracted for analysis.

Table 2. Pilot study instruments

Instrument	**Purpose**	**Administered**	**Time to complete (min)**	**Timepoints Intervention**	**Timepoints Comparator**
Enrollment form	To obtain contact information and preferences, emergency contact information, and sharing of information with primary care provider	Self	5	Baseline	Baseline
Data collection form	Baseline data and to measure changes over time on participant characteristics (including demographics), health conditions, and health habits	Self	10 5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo, 12mo
Physical activity journal	To track usual physical activity over a week and over time	Self	10/ week	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Nutrition journal	To track usual eating content and habits over a week and over time	Self	10/week	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Health and wellness learning session worksheets	To reflect on personal habits and reasons for change	Self	5-30/week	In health and wellness learning sessions and for reflection between sessions	

Goals, action plan and barrier identification	To develop personalized plan for sustainable lifestyle changes and to identify barriers	Team members and participants	Initial 45-60; Follow-up 10-15	Monthly in individual sessions	Baseline, 3mo, 6mo, 9mo,12mo
Physical Activity Readiness Questionnaire for Everyone PAR-Q+	Physical activity readiness	Self	3	Baseline	Baseline
SF-36, Health Utilities Index (HUI)2/3	Quality of life	Self	5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Patient Health Questionnaire (PHQ)	Baseline and change over time for depression and anxiety	Self	5	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Insomnia Severity Index (ISI)	Baseline and change over time of insomnia	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Perceived stress scale	Baseline and change over time of perceived stress	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Life Change Index Scale	Baseline and change over time of stressors	Self	3	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
DeJong Gierveld Loneliness Scale	Baseline and change over time for loneliness	Self	2	Baseline, 3mo, 6mo, 9mo,12mo	Baseline, 3mo, 6mo, 9mo,12mo
Participant satisfaction surveys	To measure participant satisfaction and improve program	Self	10	3mo, 6mo, 9mo	3mo, 6mo, 9mo
Costs and medical utilization log	To measure direct costs and medical utilization	Self	Variable	Continuous	Continuous

Data analysis

Quantitative

See Table 1 for a description of the objectives of the study, outcomes measured, and analytic techniques for each component. Quantitative data will be reviewed for missing data and entered into Excel and/or SPSS. Descriptive statistics will be presented for the participants in the study. Changes within groups over time will be assessed with t-tests, for specific time points, and repeated measures ANOVA, and differences between groups will be assessed using generalized estimating equations (GEE). Since this is a pilot study, this information will be looked at to help inform a larger randomized trial. Total costs for the program will be recorded through administrative data, and cost-effectiveness analyses will be conducted to the extent possible using data provided by participants on the costs and medical utilization logs. This pilot study will allow testing of the costs and medical utilization log instrument.

Qualitative

Transcripts, field notes, and documents will be coded using Microsoft Word. Concepts and themes will be developed using a constant comparative method of analysis in which new information is compared to previous information. Themes related to the concept of the program, implementation of the program and feasibility will be developed, among others. Confirming and disconfirming evidence will be sought to ensure data saturation or completeness of the findings.[67]

Data and participant monitoring

Team members will meet weekly to discuss study progress and review data quality and monitoring of attendance or any concerns raised by participants or clinicians.

Participants will fill out mental health scales, which will be scored during data collection in REDCap. Research assistants will have training on interpreting these scales. If any concerns around these findings or other signs of deterioration are encountered by anyone on the research or program teams, the principal investigator or alternate clinician will be notified while the participant is still in contact with the team member. An assessment will be conducted, and if any concerns arise for self harm or harm to others, proper guidelines will be followed, including creating a safety plan, contacting the participant's family physician and/or providing more frequent follow-ups, or contacting emergency services, as deemed appropriate.[68]

Few risks are anticipated for this study. However, there could be anxiety or fatigue caused by participating in the study or in filling out the forms. If any concerns are noted, the principal investigator will attend to these concerns and may remove the participant from the study, following a discussion with the participant and the team, if this is deemed in the participant's best interests. This study does not require a data and safety monitoring board since there are no drugs or devices being tested and is considered low risk.

ETHICS AND DISSEMINATION

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. If any changes are made to the research design, HiREB will be notified and changes will be made based on their recommendations. A research assistant will explain the nature of the study to potential participants, their rights as participants, confidentiality of their data, voluntary entry into the study, and their ability to withdraw from the study at any time.[69, 70] There is minimal risk of entering this study, however, participants will be informed about the potential risks of unintended disclosure, where they may potentially give away information about themselves or about a third party during qualitative exit interviews which could lead to recognition of themselves or the third party,in which case confidentiality will be sought for the third party as well by ensuring no identifying quotes are used in publications. In addition, there are some risks to starting or increasing any exercise activity, such as injury. However, the benefits of increasing mobility outweigh most of the risks of potential injury and having trained team members and setting realistic goals will allow for gradual adjustments in their mobility levels. Any questions will be answered, and informed consent will be obtained prior to enrolling any participant into the study. All data gathered for the study will be kept confidential by using identifiers (with identifiers and identifying data kept separately), and access will only be given to the research team members. Paper documents will be stored in a locked cabinet. Electronic documents will be kept on password-protected computers. All data will be input into REDCap, which requires a password and tracks users. Participants will have the option to provide consent for sharing of information with their primary care or other treating physician(s). No information will be released without the participant's consent, unless ordered through a court or in the case of harm to self or others, where participant information may need to be released for emergency treatment. This information is stated in the informed consent form. In the case of a data breach, the privacy officer will be contacted as soon as the breach is detected and McMaster University protocols will be followed.

Participants in both arms will receive a modest monetary compensation of $30 each time they meet with the research assistant for data collection every three months for an expected time of 1 hour (5 times total). This amount is seen as a token of appreciation yet non-coercive. Comparator-arm participants will also be allowed to participate in the healthy lifestyles program at a later date on the condition that the program is still running.

Timeline and activities and knowledge translation

The pilot phase will take approximately 24 months (beginning in April 2018 and ending in April 2020), which includes time for recruiting participants, planning logistics, running the full program, analyzing data, and generating knowledge translation activities. Knowledge exchange will include feedback from participants, staff, health providers and family members. Peer-reviewed publications and presentations at conferences (e.g., family medicine, public health) will target researchers and health professionals. Policymakers and other stakeholders will be engaged to identify needs and any policy implications of the findings.

Post-trial care

Participants will continue to receive usual care from their primary care physicians during and after the study.

DISCUSSION

This pilot phase will assess the feasibility and implementation of a healthy lifestyles program. In the longer-term, findings of this and future research in this area are expected to address gaps in knowledge around individuals' attainment of healthier lifestyles, on health services organization, and on community and policy efforts to support these changes. The impact on participant experiences and outcomes is one of the main objectives of this study. The healthy lifestyles program is person-centered in that it allows for participants to self-identify relevant health goals and to develop realistic and sustainable action plans to achieve their goals. The purpose of evaluating the healthy lifestyles program is to understand if and how it works, to iteratively improve the program, and to understand the implementation process so that it can be scaled up successfully in other sites.

List of abbreviations

BMI – Body mass index

CBC – Complete blood count

CBT – Cognitive behavioural therapy

EOSS - Edmonton Obesity Staging System

GEE - Generalized estimating equations

HiREB – Hamilton Integrated Research Ethics Board

HUI – Health Utilities Index

ISI – Insomnia Severity Index

PAR-Q+ - Physical Activity Readiness Questionnaire for Everyone

PHQ – Patient Health Questionnaire

RAND SF36 – 36-Item Short Form Survey

Declarations

Ethics approval and consent to participate

Approval from the Hamilton Integrated Research Ethics Board (HiREB) has been obtained. Project number: 3793

Competing interest

D.F. has a proprietary interest in Health Utilities Incorporated, Dundas, ON, Canada. HUI Inc. distributes copyrighted Health Utilities Index (HUI) materials and provides methodological advice on the use of the HUI. The other authors declare no conflict of interest.

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Author's contributions

EA developed the research question and protocol. EA and MQ drafted the manuscript. JS, AS and EA revised the manuscript. EA, MQ, LM, JL, CL, MW, ZS and DF contributed to the design of the protocol. JF contributed to the conceptual design of the work. All authors read and approved the final manuscript.

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Figure 1 Legend:

Figure 1. PRECIS-2 wheel for the healthy lifestyles program pilot trial design. This figure was created by reaching a consensus for each domain from four investigators on the study team using a 1 to 5 ordinal scale from explanatory (blue line towards the centre) to pragmatic (blue line towards the periphery).[71] Aside from the *organization* domain, the PRECIS-2 wheel illustrates that the study design is closer to a pragmatic than an explanatory trial (see appendix 1).

Appendix 1:

Trial design characteristics

According to the PRagmatic-Explanatory Continuum Indicator Summary (PRECIS2) criteria, the HLP design favours a pragmatic trial (figure 1). Figure 1 was created by reaching a consensus for each domain from four investigators on the study team using a 1 to 5 ordinal scale from explanatory to pragmatic.[71] (1) The eligibility criteria allows for a broadly representative population. However, those who do not speak English and/ or have unstable physical or mental health concerns will be excluded. (2) Participants will be recruited from the community. (3). The trial is being conducted in a community based setting. (4) Any physician or advanced practice healthcare provider familiar with the principles of cognitive behaviour therapy and health behaviour would be able to develop goals, action plans and conduct education sessions. However, specialized providers including a dietician will be part of the trial. (5) Delivery of educational sessions and goal setting will be flexible, however, there will be some restrictions based on participant and provider availability. (6) Participants will have the choice to attend as few or as many sessions as they would like. (7) Participants enrolled in the healthy lifestyles program will be followed with more frequent visits and more extensive data collection than would occur during usual care routines. (8) The primary outcome of goal attainment will be a meaningful outcome to the study participants. (9) Due to the small sample size of the pilot study there will be no intention to treat analysis. Overall, most of the PRECIS-2 domains for the pilot study were assessed to be pragmatic, though this appraisal is potentially biased since it was conducted by investigators associated with the study.[72]

90x90mm (300 x 300 DPI)

Letter of information/consent – Participation in healthy lifestyles program

Title of study: Evaluating a healthy lifestyles program

Principal investigator: Elizabeth Alvarez, MD, MPH, PhD, CMCBT

Co-investigator(s): Lawrence Mbuagbaw, MD, MPH, PhD; Majdi Qutob, MD, MSc, MBA; Cynthia Lokker, PhD; Marjan Walli-Attaei, PhD candidate; John N. Lavis, MD, PhD; Zena Samaan, MD, MSc, MRCPsych, PhD

You are being invited to participate in a research study. The purpose of the study is to evaluate a healthy lifestyles program. Specifically, you are being invited to participate in a year-long program geared to helping people make healthy lifestyle changes. If you agree to participate in this study, you will be randomly assigned (chosen by chance) to either a more intensive program or a less intensive program. Either program will be run out of the David Braley Health Sciences Centre on 100 Main Street West in Hamilton, Ontario. You will need to secure transportation to and from the site. If you are not able to afford transportation, please ask the research assistant for possible supports, although they are not guaranteed.

Both programs, the more intensive and the less intensive programs, will help you identify health goals and track how you are doing in meeting those goals throughout the year.

The **more intensive program** will include hour-long evening group meetings once a week to either learn about health and wellness strategies or to have facilitated group discussions on meeting goals. If you are selected to be in the more intensive program, *please note* – the group meetings are considered confidential, and we ask that you and others do not share the information with people who are not part of the meeting. In addition, the more intensive program will include individual meetings with a healthcare team once a month. The initial meeting is expected to last three hours and the follow-up meetings are an hour each. These will be scheduled once the study begins.

The **less intensive program** will include individual meetings once every three months with a research assistant trained in health behaviour theories (five times total). The initial meeting is expected to last two hours and the follow-up meetings are an hour each. These will be scheduled once the study begins. If you are selected to be in the less intensive program, you will be offered the opportunity to participate in the more intensive program once the study ends, given the continuation of the program.

As part of the study in either program, information will be collected about you (for example, your age, marital status, etc.), your current and past health (for example, medical problems and medications you are taking to treat those problems, etc.), and current health habits (for example, if you smoke, how often you exercise, etc.). You will be asked to fill out surveys about your

health (for example, stress levels, symptoms of anxiety) and about the program (for example, what parts of the program are useful, recommendations for improving the program, etc.). In addition, you will be asked to have your height, weight, waist circumference (measurement around your waist), waist hip ratio (measurements around your waist and hips), and blood pressure taken. You may also be asked to have blood drawn once at the beginning of the study and up to five times throughout the year only if you meet the requirements for screening or if you have certain health conditions, such as diabetes or heart problems. If your doctor already has this information, we will ask you to provide this information instead of having you do additional bloodwork. Every three months, you will be provided and asked to fill out a nutrition journal for a week and a physical activity journal for a week (five times total) to help you reflect on your health goals and to gather information on lifestyles. You will receive reminders to complete these forms at the appropriate times. In addition, you will be asked to keep track of costs related to healthcare (e.g., transportation, parking, medications) and the use of medical services throughout the year through a log that will be provided. Lastly, you will be asked to participate in an exit interview to gather your thoughts on the program and ways to improve the future design of the program. These interviews will be audio-recorded, with your permission. Notes will be taken during these interviews and recordings will be transcribed.

Please note – even though there is a physician on the team, Dr. Elizabeth Alvarez, and she will review the findings or address concerns brought forward by the research assistants related to your health, you are expected to see your personal doctor for your healthcare needs. Dr. Alvarez will be in contact with your primary care doctor if any changes to your health status are noted or concerns are identified. You will be asked to sign a form to allow Dr. Alvarez and the team to share information about your health with your primary care doctor. This sharing of information will only happen if you agree to this. *Please note* - In the event it is deemed that you are at risk of self-harm or harm to others, appropriate protocols will need to be followed for ensuring your or others' safety. This means personal information may need to be provided to emergency care workers or the authorities, if others are involved.

As part of this study, we are also seeking to understand the role of family members in creating and maintaining healthy lifestyles. We will ask for you to provide information to your family members about halfway through the program about their participation in focus groups to help gather their perspectives. Your ability to pass on this information is voluntary, and their participation is also voluntary. More information will be provided at the appropriate time.

Appropriate and respectful behaviour is expected from all people participating in this study at all times, including participants and team members. If anyone becomes belligerent, swears, uses inappropriate language or behaviours, etc., s/he can be removed from the study at the discretion of the team members.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may choose to withdraw from the study at any time. We cannot promise any personal benefits to you from your participation in this study. However, it is expected that you will be able to set healthy lifestyle goals. The program is provided free of cost to you. In addition, you will receive $30 each time data is collected. This means that each time the research assistant meets with you once every three months (five times total), you will receive $30.

There are minimal risks associated with this study. There are some risks involved in starting new exercise programs, such as injuries. Appropriate goal setting will help minimize this risk. You may feel anxious or fatigued when filling out documents or during the course of the program. If so, the team will help you identify these concerns and solve them or remove you from the study after discussing this with you. There is also a risk of disclosure where you or another participant may be able to identify comments made by you. Every attempt will be made to present information in a way that does not identify individuals.

Any information gathered about you during this study will be treated as confidential. We will ensure that documents are kept in a locked cabinet and electronic records are stored on a security protected computer and only the research team will have access to this information. The documents and records will be destroyed after 10 years from the end of the study, which is the standard for research in Canada. We will make the summary of our findings publicly available for use by others interested in improving their efforts to support healthy lifestyle changes and chronic disease management.

Your anonymity as a research study participant will be safeguarded. We will ensure that the list of study participants and their participant numbers will be stored in a different locked cabinet or security protected file from those where the documents or electronic records are kept for the purposes of the study. Every effort will be made to report information in a way that will not identify individual respondents; however, there is a slight chance that someone may be recognizable by his/her comments.

Please check yes or no to the questions below to indicate whether you consent to participate in our study. We would be pleased to provide you with additional information about our study and your potential participation. Please see contact information below if you have any questions about entering the study or while you are enrolled in the study. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board may consult your research data. However, no records which identify you – be it name or initials will be allowed to leave the university. By signing this consent form, you authorize such access.

Request for consent	Yes	No
1. I am willing to participate in a year-long research program as described above		
2. I understand that I am able to withdraw from the study at any time with no consequences to my care from my current health providers		
3. I understand that my personal information will be kept confidential and all attempts will be made to keep my information anonymous		
4. I understand that in the event I am deemed to be a harm to myself or others, the team will follow appropriate protocols, which may mean information is provided to emergency personnel or authorities, if others are involved.		

5. I understand that selection into the more intensive or less intensive programs will be based on chance selection. If I am in the less intensive program, I will be offered the opportunity to participate in the more intensive program once the study ends, given the continuation of the program.		
6. If I am selected to be in the more intensive program, I understand that information presented by others during group meetings is to be treated in a confidential way, that is, I will not share information with people outside of the meeting		
7. I understand there are some risks involved in starting new exercise programs, such as injuries, but efforts will be taken to minimize these risks		
8. I understand that I need to seek regular care from my family doctor outside of this program. The team will not provide acute care unless it is an emergency and does not replace my family doctor's care. Changes in drug treatment will not be done through this program, including the writing of prescriptions.		
9. I understand that the team will only communicate with my family doctor if I approve this.		
10. I understand that my exit interview will be audiorecorded.		
11. Please contact me. I would like additional information about the study and/or my participation.		

I will receive a signed copy of this form.

Participant

Print name: _____ Signature:_____

Date: _____

Person obtaining consent

Print name: _____ Signature:_____

Date: _____

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HIREB at 1-905-521-2100 x 42013.

Sincerely,

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___2_____
	2b	All items from the World Health Organization Trial Registration Data Set	___N/A_____
Protocol version	3	Date and version identifier	File name
Funding	4	Sources and types of financial, material, and other support	___15_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Cover and pg. 15
	5b	Name and contact information for the trial sponsor	Author – cover pg
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___15_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___13_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	6 and Table 1
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9 and Appendix 1
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	5-6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9 and 13

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__9-11, 13_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Table 1 and pg. 12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___13_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___8_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___13_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___N/A_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___13_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___13_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___13_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___15_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Informed consent
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___14_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	____14_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	Standard authorship guidelines will be used – not reported
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Protocol on ClinicalTrials.gov, others N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Informed consent forms, not included

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	__N.A_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.