



# 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-centred and evidence-based and practice-based programme has been created to address these needs. This proposal aims to evaluate the feasibility and implementation of this programme 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 programme. The pilot study includes a randomised controlled trial, with 30 participants randomised to either the programme or to a comparator arm, and qualitative components to determine the feasibility of the programme, including recruitment and retention, data missing rates and resources needed to run this programme. Changes in participant-directed and clinical outcomes will be measured. Descriptive statistics, t-tests and repeated measures analysis of variance (ANOVA) for within group comparisons and generalised estimating equations for between group analyses will be used. Qualitative interviews of programme staff and healthcare providers and family focus groups will be used to further enhance the findings and improve the programme.

**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.

## Strengths and limitations of this study

- Integration of quantitative and qualitative data are used to holistically evaluate the healthy lifestyles programme.
- 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.

**Trial registration number** ClinicalTrials.gov Identifier: NCT03258138.  
HiREB project number: 3793.

## INTRODUCTION

Chronic conditions, such as diabetes, cardiovascular disease and obesity, are rising in Canada and internationally.<sup>1–6</sup> In addition, 1 out of every 3 Canadians meet the criteria for mental or substance use disorder at some point in their lives.<sup>7</sup> These chronic conditions can, on their own or as co-morbidities, impact the quantity and quality of people's lives.<sup>4 8–12</sup> The link between mental and physical health is well-established in the literature.<sup>10–12</sup> 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.<sup>13</sup>

Risk factors, including tobacco use, unhealthy diet and physical inactivity, are partially responsible for this rise in chronic diseases.<sup>4 14</sup> Mental health is also affected by poor lifestyle habits.<sup>14 15</sup> 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.<sup>16–18</sup> However, even if people know the benefits of having healthier habits, there is often a gap in ‘how to’ make these changes.<sup>19</sup>

Setting goals can be integral in changing behaviour and improving health.<sup>20</sup> Goals that centre around behavioural changes, such as working out for thirty minutes every day, compared with physiological changes, such as losing five pounds, are advantageous, as they are under a person’s direct control and can result in observable changes.<sup>20</sup> Individuals also exhibit greater commitment to behavioural changes when goals are personalised.<sup>20</sup> However, sometimes setting goals is insufficient to instigate behavioural changes.<sup>21</sup> 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.<sup>22</sup> 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.<sup>21</sup>

Lifestyle programmes that incorporate cognitive behavioural therapy (CBT) have been shown to help with weight loss, insomnia, anxiety and depression.<sup>23–26</sup> CBT is a type of psychotherapy that focuses on challenging dysfunctional or negative cognitions and beliefs and addressing maladaptive behaviours.<sup>27</sup> In addition, interventions designed with a theoretical foundation have been shown to be more successful than those without a theoretical base.<sup>28</sup> In particular, an ecological approach to behaviour change allows for the inclusion and assessment of factors at the individual, interpersonal, institutional or community and policy levels.<sup>29</sup> 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 programmes need to account for concurrent conditions and physical limitations. This type of person-centred care is a different approach than simply bringing more services to one location, or having services follow individuals.<sup>30–32</sup> This person-centred 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-centred 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 programmes, focus only on secondary or tertiary prevention, or neglect the role of mental health or the determinants of health in lifestyle changes.<sup>33–35</sup> A new, multidisciplinary, person-centred, and evidence-based and practice-based healthy lifestyles programme has been created to address these needs.<sup>36</sup> This proposal aims to evaluate the feasibility and implementation of a healthy lifestyles programme through a pilot study.

### Novel intervention

Individuals will be enrolled in a healthy lifestyles programme (HLP) for 1 year. This amount of time will allow for determination of participant goals, identification of barriers and facilitators, healthy lifestyle education and modification of individualised 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-based and practice-based recommendations for healthy lifestyles.<sup>23 29 36–38</sup>

These will provide the basis for the individualised action plans. Monthly individual sessions with a family physician trained in CBT, a dietician and a physical therapist will help individuals tailor their action plans to their particular circumstances and needs.<sup>39 40</sup> 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 programme. Participants will also receive help in finding community programmes to support healthy lifestyles.

A preliminary programme manual has been developed. Education sessions include: S—Session; S1—Introduction to Programme; 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 well-being and chronic pain; S18—Revisiting goals and reflecting on self-growth. The first eight 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 programme manual will be updated following this pilot study. A graduation ceremony will be provided for programme 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 pretrial test run (Summer 2017) with nine volunteers enhanced the style of delivery, format and content of the first eight health and wellness learning sessions and the initial assessment segments of the programme. As a form of concept testing, feedback from the pretrial sessions informed the content and structure of the programme and reinforced the potential of the programme 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.<sup>41 42</sup> In order to evaluate the specific parameters of the healthy lifestyles programme that may influence its effectiveness, cost, duration, frequency and intensity, a comparator group that will set goals and action plans has been chosen.<sup>41</sup> 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 3 months to develop personalised 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 programme, based on CBT and behavioural theories provided through group and individual sessions along with usual care, compared with development of health goals and action plans along with usual care help meet participant-directed and clinical outcomes for adults? We hypothesise that the healthy lifestyles programme will be feasible and more effective for helping participants meet their health goals compared with 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 programme. This pilot study will also identify the conditions for a larger randomised controlled trial. Evaluating the context, including the site and materials used, of this pilot phase will help determine if, and how, the programme 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.

## 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.*<sup>33</sup> This will allow for the flexibility needed to study multiple dimensions of a new programme, especially one designed for creating healthy lifestyles through the development of participant-directed goals and individualised action plans.<sup>43–46</sup> Elements of both concurrent and embedded mixed methods designs will allow for quantitative and qualitative data to be used to inform aspects of the programme, 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.<sup>46</sup> 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 programme and to test and inform the programme.<sup>46</sup>

This study will not be blinded as the amount of exposure to the programme 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 generalisability of findings (see [figure 1](#)).<sup>43</sup> 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 randomised 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 programme staff and participants' health-care providers at 6 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 programme 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 programme, or its delivery, while the study continues.

### Patient and public involvement

People with chronic conditions were part of the pretrial test run of the programme and helped develop the protocol as collaborators. In addition, as a person-centred programme, participants will be involved in the development of relevant personal goals and their scales. They will also provide feedback on the programme throughout the study through participant surveys. This feedback will be used pragmatically to shape the programme during the study, if needed, to fit participants' needs. Any changes made will be noted in the final report. All collaborators



**Table 1** Study objectives, outcomes and analysis plans

Objectives	Outcomes	Analysis	Hypothesis
<b>Primary</b>			
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 Descriptive statistics, cost analysis Descriptive statistics and thematic analysis for open-ended questions Thematic analysis Thematic analysis Thematic analysis Thematic analysis
	Assess resources needed to run programme	Health professionals needed, numbers and sizes of rooms needed for group and individual sessions, materials needed, costs and medical utilisation logs	
	Participant feedback	Participant satisfaction surveys	
		Qualitative individual exit interviews	
	Staff feedback	Individual staff interviews	
	Family member feedback	Family focus groups	
	Healthcare provider feedback	Individual healthcare provider interviews	
<b>Secondary</b>			
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 generalised estimating equations for between group analyses.
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 movement in meeting goals The intervention group will show greater improvement in these measures

ANOVA, Analysis of variance; BMI, body mass index; CBC, complete blood count; HbA1c, Hemoglobin A1c

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 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 programmes 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 coauthors who have practice and research experience in these areas.

### Sampling and recruitment

Participants in the randomised 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



**Figure 1** PRagmatic-Explanatory continuum indicator summary (PRECIS-2) wheel for the healthy lifestyles programme pilot trial design. This figure was created by reaching a consensus for each domain from four investigators on the study team using a 1–5 ordinal scale from explanatory (blue line towards the centre) to pragmatic (blue line towards the periphery).<sup>71</sup> Aside from the organisation domain, the PRECIS-2 wheel illustrates that the study design is closer to a pragmatic than an explanatory trial. Trial design characteristics: according to the PRECIS-2 criteria, the HLP design favours a pragmatic trial. This figure was created by reaching a consensus for each domain from four investigators on the study team using a 1–5 ordinal scale from explanatory to pragmatic.<sup>71</sup> (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, specialised 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 programme 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.<sup>72</sup>

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 randomised 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 among participants.<sup>23–26</sup>

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 programme 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 enrol participants into the study. Healthcare professionals involved with routine participant care or with the conduct of the programme 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 programme evaluation. Recruitment will continue until the programme starts, if needed.

#### Sampling and recruitment for qualitative components

All participants and programme 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 randomisation

Each participant will be assigned a random number using the RAND function on Excel. Participants will be allocated to the healthy lifestyles programme 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 randomised by the lowest number. A research assistant not involved in the recruitment or in the programme 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 programme 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,

**Table 2** Pilot study instruments

<b>Instrument</b>	<b>Purpose</b>	<b>Administered</b>	<b>Time to complete (min)</b>	<b>Timepoints intervention</b>	<b>Timepoints comparator</b>
Enrolment 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, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Physical activity journal	To track usual physical activity over a week and over time	Self	10/week	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Nutrition journal	To track usual eating content and habits over a week and over time	Self	10/week	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
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 personalised 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, 3, 6, 9, 12 months
Physical activity readiness questionnaire for everyone PAR-Q+	Physical activity readiness	Self	3	Baseline	Baseline
SF-36, Health Utilities Index 2/3	Quality of life	Self	5	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Patient Health Questionnaire	Baseline and change over time for depression and anxiety	Self	5	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Insomnia Severity Index	Baseline and change over time of insomnia	Self	2	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Perceived stress scale	Baseline and change over time of perceived stress	Self	2	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Life change index scale	Baseline and change over time of stressors	Self	3	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
DeJong Gierveld loneliness scale	Baseline and change over time for loneliness	Self	2	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
Participant satisfaction surveys	To measure participant satisfaction and improve programme	Self	10	3, 6, 9	3, 6, 9 months
Costs and medical utilisation log	To measure direct costs and medical utilisation	Self	Variable	Continuous	Continuous

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 programme 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.<sup>47–49</sup> 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<sup>48</sup> 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,<sup>49</sup> 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 hemoglobin A1c (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.<sup>50 51</sup> 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, body mass index, waist circumference, waist:hip ratio and Edmonton Obesity Staging System (if relevant).<sup>52</sup>

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 utilisation log will be provided to participants and collected once every 3 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 well-being scales will be filled out by participants at baseline and every 3 months to assess change in these indicators (five times total). The Physical Activity Readiness Questionnaire for Everyone 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 programme. The 36-Item Short Form Survey (RAND SF-36)<sup>53 54</sup> and Health Utilities Index 2/3<sup>55–57</sup> 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 (Generalized Anxiety Disorder 7 or GAD-7), bulimia, somatoform disorders and alcohol misuse.<sup>58–60</sup> The Insomnia Severity Index identifies insomnia symptoms.<sup>61</sup> The Life Change Index Scale, otherwise known as the Holmes and Rahe stress scale, has been found to correlate with medical utilisation in a family practice setting.<sup>62</sup> In addition, the Perceived Stress Scale measures the degree to which situations in one’s life are perceived as stressful.<sup>63 64</sup> Lastly, the DeJong Gierveld 6-item Loneliness Scale captures both emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network).<sup>65 66</sup>

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

## 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 analysis of variance (ANOVA), and differences between groups will be assessed using generalised estimating equations. Since this is a pilot study, this information will be looked at to help inform a larger randomised trial. Total costs for the programme 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 utilisation logs. This pilot study will allow testing of the costs and medical utilisation 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 with previous information. Themes related to the concept of the programme, implementation of the programme and feasibility will be developed, among others. Confirming and disconfirming evidence will be sought to ensure data saturation or completeness of the findings.<sup>67</sup>

## 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 programme 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.<sup>68</sup>

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.<sup>69 70</sup> 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 \$30CAD each time they meet with the research assistant for data collection every 3 months for an expected time of 1 hour (five 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 programme at a later date on the condition that the programme 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 programme, analysing 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 (eg, 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 programme. 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 organisation 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 programme is person-centred 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 programme is to understand if and how it works, to iteratively improve the programme and to understand the implementation process so that it can be scaled up successfully in other sites.

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**Competing interests** DF 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.

**Patient consent for publication** Not required.

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

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