FEASIBILITY STUDY OF THE HEALTHY LIFESTYLES PROGRAM

A PILOT PRAGMATIC RANDOMIZED CONTROLLED TRIAL OF A 12-MONTH HEALTHY LIFESTYLES PROGRAM

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Lay Abstract

Rates of chronic physical and mental health illness are rising in Canada. Lifestyle or behavioural changes can prevent or manage chronic diseases. The aim of this pilot study is to test the feasibility of delivering a 12-month Healthy Lifestyles Program to participants in Hamilton, Canada. The Healthy Lifestyles Program is a complex intervention designed to help participants identify health goals and action plans to achieve those goals with the guidance of healthcare professionals. We observed that the program was successfully delivered, accepted by participants and staff and required minor changes to the study design for a scaled-up study. The program showed positive trends for improving goal attainment, depression, and loneliness scores. The results of this study will help inform the design and scale-up of a larger study.

Abstract

Background: The primary objective of this study was to assess the feasibility of the Healthy Lifestyles Program (HLP), a novel 12-month complex intervention based in cognitive behavioural therapy and theories of behavioural change, delivered in a community-based setting in Hamilton, Canada. The secondary objective was to explore implementation factors.

Methods/ design: A pragmatic pilot randomised controlled trial using quantitative and qualitative evaluation methods. Participants were randomly allocated to either intervention group (n=15) or comparator group (n=15). The intervention group attended weekly group education sessions and met in-person with a healthcare team monthly to create personalized health goals and action plans. The comparator group met with a research assistant every three months to develop health goals and action plans. We assessed feasibility of the program by measuring recruitment, participation and retention rates, missing data, and attendance. All participant-directed and clinical outcome measures were analyzed for between and within group changes using Generalized Estimating Equations (GEE). Content analysis was conducted for qualitative data.

Results: We recruited and randomized 30 participants to each group (n=15) within 3 months. Retention rate was 60% (9/15) for the intervention group and 47% (7/15) for the comparator group. Less than 1% of participant-directed and clinical outcomes were missing. Participants attended an average of 29 of 43 educational sessions and 100% of one-to-one sessions. The healthcare team valued the program's holistic approach to care, increased time and interaction

with participants, professional collaboration, and the ability to provide counselling and health supports. Location accessibility was an important factor facilitating implementation. Reducing the number of psycho-social education sessions and having access to a gym could improve retention and delivery of the program.

Conclusion: This study has demonstrated the feasibility of the HLP with minor modifications recommended for a larger trial and for the intervention.

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List of Abbreviations

AR	Autoregressive
BMI	Body Mass Index
CBT	Cognitive Behavioural Therapy
CONSORT	Consolidated Standards of Reporting Trials
COVID-19	Coronavirus Disease 2019
DBHS	David Braley Health Sciences Centre
DSM-IV4	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
DGJLS	DeJong Gierveld Loneliness Scale
GAD-7	General Anxiety Disorder 7
GEE	Generalized Estimating Equations
HLP	Healthy Lifestyles Program
HUI2	Health Utility Index Mark 2
HUI3	Health Utility Index Mark 3
IC/ES	formally known as the Institute for Clinical Evaluative Sciences
ISI	Insomnia Severity Index
LCIS	Life Change Index Scale
MCID	Minimal Clinically Important Difference
MCS	Mental Component Summary
OHIP	Ontario Health Insurance Plan
PAR-Q+	Physical Activity Readiness Questionnaire
PCS	Physical Component Summary
PHQ9	Patient Health Questionnaire 9
PRECIS2	PRagmatic-Explanatory Continuum Indicator Summary
PSS	Perceived Stress Scale
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
REDCap	Research Electronic Data Capture
SF	Short Form
TCPS 2: CORE	Tri- Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics
WHO	World Health Organization

Declaration of Academic Achievement

Japteg Singh was the primary author of the current paper, assisted with data collection, and led the analysis and interpretation of findings. This project was supervised by Dr. Elizabeth Alvarez, who designed the Healthy Lifestyles Program, provided guidance throughout the study process, and edited this paper. Dr. Rebecca Ganann and Dr. Lawrence Mbuagbaw provided guidance and feedback regarding the structure, analysis, and interpretation of this paper.

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BACKGROUND

An estimated third of Canadian adults live with at least one major chronic disease, while two-thirds of all deaths are attributed to four kinds of chronic diseases: cancer, diabetes, cardiovascular and chronic respiratory diseases.[1,2] The prevalence of modifiable risk factors across Canada is high, with about 80% of Canadian adults (20 years and older) exhibiting one or more modifiable risk factor.[1] These risk factors include: heavy drinking, smoking (daily or occasional), physical inactivity, and low consumption of fruits and vegetables amounting to less than five servings per day. In Ontario, chronic diseases account for about 75% of all deaths and chronic disease management is estimated to be 10.5 billion a year in direct healthcare costs.[3] Specifically, Ontario's annual estimated total direct healthcare costs associated with modifiable risk factors are $7 billion for tobacco smoking, $4.5 billion for alcohol consumption, $3.6 billion for physical inactivity, and $5.6 billion for unhealthy eating ($1.8 billion for inadequate vegetable and fruit consumption).[3] Therefore, addressing the emerging epidemic of chronic diseases by addressing behavioural risk factors is crucial to minimize their health and economic burden.

There is a bidirectional link between physical and mental health conditions that adversely affects health outcomes.[4–7] Depression and anxiety are common mental health illnesses associated with the majority of chronic physical conditions.[8,9] Studies show that depression and anxiety are increased among individuals living with a chronic condition such as diabetes, cardiovascular diseases, inflammatory diseases, etc. [5,10–15] Conversely, observational studies suggest that individuals living with a mental illness, like depression, have a greater likelihood of chronic conditions.[16–20] For example, a review of four qualitative studies revealed that patients with cardiovascular disorders indicated that anxiety and depression were major contributing

factors that inhibited their ability to cope and self-manage their chronic conditions.[21] The ability to self-care and manage one's chronic conditions can be affected by poor mental health outcomes like depression and anxiety.[22] Additionally, mental health is affected by poor lifestyle habits leading to a vicious cycle of worsening physical and mental health, with social implications, such as social isolation, and further worsening of symptoms.[23]

Promotion of Healthy Lifestyles

The World Health Organization (WHO) views lifestyles as specific and definable behavioural patterns, which influence health outcomes, but most importantly are modifiable.[24] Therefore, over the past twenty years, the WHO has prioritized the need to address lifestyle factors by promoting healthy lifestyle behaviours and mitigating unhealthy ones. [24] Although there are multiple operational definitions for lifestyle interventions, all definitions share a few key similarities. Broadly, lifestyle interventions include the application of evidence-based practices to help individuals adopt and sustain behavioural changes in diet, exercise, sleep, stress, substance-use, and social supports to prevent, manage and reverse lifestyle-related chronic diseases.[25–27]

Many risk factors for chronic diseases and multimorbidity are behavioural and lifestyle-related.[28] Canadians are more likely to discuss lifestyle behaviours with their primary care provider than populations from other developed countries.[29] However, lifestyle interventions are often designed and applied in controlled research settings, and rarely evaluate process measures, making them difficult to translate to real-world contexts.[30–32] This is because lifestyle or behavioural interventions implemented at the community level are often short-term (less than 6 months), have reduced effect sizes compared to explanatory studies, are under-funded and often lack engagement with stakeholders, limiting their relevance (i.e., contextual and cultural) to the

target population and existing networks.[31,33] Additionally, there is often a gap in knowledge regarding how to make and sustain lifestyle changes, especially in real life settings.[32] In a review of qualitative studies examining the barriers and facilitators to implementing lifestyle interventions to prevent cardiometabolic disease, commonly cited professional barriers by primary care physicians included the lack counselling skills, education, knowledge and experience to address lifestyle changes.[34] Other cited barriers were structural (e.g., time restraints, lack of awareness of existing guidelines, lack of evidence and/or guidelines on prevention, or too many guidelines for a specific purpose), organizational (e.g., communication barriers among health teams, lack of support), patient related factors (e.g., low adherence), and attitudinal (e.g., negative attitudes towards prevention interventions).[34]

The Healthy Lifestyles Program

The Healthy Lifestyles Program (HLP) is a holistic, person-centred behavioural change intervention that targets self-identified lifestyle goals to improve health outcomes through a combination of individual and group modalities. It is a program aimed at enhancing physical activity, social participation, and nutrition while addressing mental health in a manner that can be integrated into the individual's lifestyle and personal preferences, in contrast to strategies that assume a 'one-size-fits-all' approach. This program was developed from principles in Cognitive Behavioural Therapy (CBT) and theories of health behaviour, and the study protocol has been published.[35] The HLP intervention consists of collaborative-goal setting and action-planning with a healthcare team and weekly group educational sessions in addition to usual care. The comparator group consists of usual care and participant directed goal development and action-planning with a research assistant trained in theories of health behaviour.

Purpose of study

This study aimed to determine the feasibility of a 12-month pragmatic, pilot randomized controlled trial of the novel HLP delivered in a community setting for participants in Hamilton, Canada. The study findings provide a basis to inform planning and scale-up of a larger, definitive trial. Therefore, the primary objectives and hypothesis were related to protocol feasibility and determining the recruitment of participants to the study, retention rates of participants to the intervention and comparator groups over 12-months, group and individual session attendance, and missing data. The intervention was considered feasible if we recruited 30 participants, had a retention rate that was equivalent or greater than other 12-month lifestyle or behavioural change trials (30-78%) [36] or 50% for this pilot, missing data rate of less than 5%, and attendance to intervention components greater than 50%.The secondary objectives were to assess the implementation of the HLP from the perspective of participants, interventionists, participants' primary healthcare providers and family members using the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework.[37] The potential effectiveness of the intervention was assessed by measuring the change in participant-centered outcomes at 12-months and in relation to the comparator group. These include goal attainment scores, mental health (i.e., depression, stress, and loneliness), health-related quality of life, and anthropometric measures (i.e., blood pressure, height, weight, Body Mass Index (BMI), waist circumference, waist to hip ratio). We hypothesized that the intervention would show potential improvements to goal attainment scores and mental health outcomes. Description of outcomes and statistical analyses are described at length in the methods section.

METHODS

Study Design

This study is a pragmatic parallel group pilot randomized controlled trial (RCT) and we follow the Consolidated Standards of Reporting Trials (CONSORT) 2010 reporting guidelines for pilot and feasibility studies (see Appendix A)[38]. The Healthy Lifestyles Program (HLP) was developed by clinical researchers from McMaster University (Hamilton), as a community-based, person-centred lifestyle intervention consisting of the following key components: participant-centred goal development, development of individualized action plans, barrier and facilitator identification to goal attainment, and psycho-educational sessions regarding lifestyle behaviour.[3] Qualitative data from participants, interventionists, family members and healthcare providers was collected to evaluate the HLP. Thisit provided the opportunity for participants to have a voice and share their experiences across the research process, and it facilitated the opportunity to collect various types of data to enrich conclusions resulting in a deeper understanding of the program and its implementation to inform scale-up.

Pragmatic Study

The PRagmatic-Explanatory Continuum Indicator Summary (PRECIS2) was used to assess the degree at which the study was either pragmatic or explanatory.[39–41] Domains included eligibility, recruitment, setting, organization, flexibility of intervention delivery, flexibility of participant adherence, follow-up, primary outcome, and primary analysis. PRECIS2 is an accepted tool for evaluating trial designs on the pragmatic-explanatory continuum. [39–41] Each domain was evaluated on a one to five Likert scale with five being most pragmatic and one being most explanatory. The Principal Investigator and three research assistants rated each domain independently and then discussed any discrepancies until a consensus was reached.

The HLP design was assessed to be slightly more pragmatic than explanatory. Figure 1 illustrates the study design based on the nine criteria of PRECIS2. 1) The eligibility criteria would allow for a broadly representative population. However, those who do not speak English were excluded. 2) Patients were recruited in primary care settings as well as through advertisements like Coffee News, a freely circulated paper-based local publication. 3) The trial was conducted in a community-based academic setting. 4) While a primary care physician trained in CBT led the intervention team, any healthcare provider familiar with the principles of cognitive behaviour therapy and health behaviour, regardless of their background, would be able to develop goals, action plans and conduct education sessions. However, specialized providers including a dietician and musculoskeletal specialist were part of the trial resulting in organization that favours a more explanatory design. 5) Delivery of the one-to-one sessions were standardized, however, there was some flexibility in the delivery of group session content to meet the needs of participants. 6) Regarding adherence flexibility, participants had the choice to attend as few or as many group sessions as they could. 7) Participants enrolled in the intervention group were followed with more frequent visits and participants in both groups had more extensive data collection than would occur during usual care routines. 8) The outcome of goal attainment is assessed as pragmatic because goals are co-developed by both interventionists and participants and therefore have obvious meaning and significance from the participant's and interventionist's perspective. Although the goal attainment is scored on a standardized scale, goals can vary and be tailored to meet the participant's objectives and needs. For example, goals included improving healthy eating, physical activity, socialization, stress management, etc. 9) Primary analysis of data occurred using per protocol principle to explore the intervention effect when participants were fully compliant to the intervention.

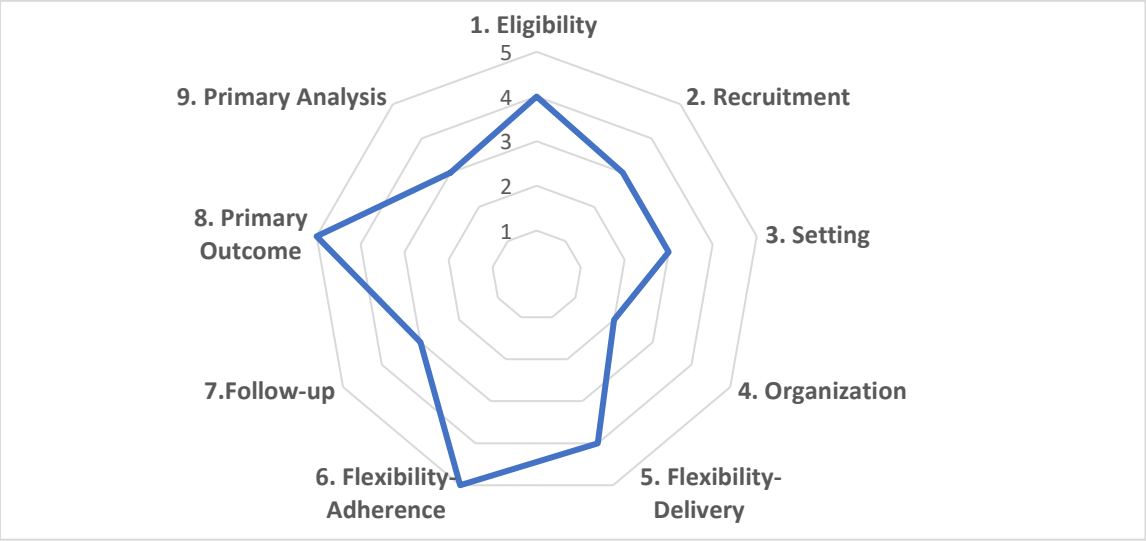

Fig. 1 PRECIS-2 wheel for HLP pilot pragmatic trial design. The PRECIS 2 wheel illustrates that the current pilot study design is closer to a pragmatic than explanatory trial.

Setting

This study was conducted at McMaster University's David Braley Health Sciences Centre (DBHS), which is centrally located in Hamilton, Ontario (Canada), during April 2018 to April 2019. This site was chosen because of its accessibility including assistive technology ensuring access for people with physical challenges (e.g., elevator access, accessible washrooms), onsite parking, and close walking proximity to public transit. Individual meetings between participants and interventionists and participant data collection occurred in closed office space settings to ensure privacy. Group psycho-educational sessions were delivered in classroom settings.

Eligibility

Study inclusion criteria included adults 18 years of age or older and able to speak English at a proficient level. For participants, the inclusion criteria ensured there were no language barriers to actively engage with the program, as it was delivered in English. There were no other exclusion criteria at the outset. However, an exclusion criterion was added during the recruitment

phase if individuals were assessed to have an unstable and untreated health condition during the informed consent process.

Recruitment and sampling

Study participants (N=30) were recruited through print and digital advertising. Recruitment posters were placed in three primary care clinics in Hamilton and in community centres, coffee shops and office buildings across Hamilton, Ontario. Paid advertisements were posted in Hamilton's local community newsletter, Coffee News, which is distributed to local stores, restaurants and coffee shops and is freely available to the public. Finally, recruitment was advertised through Twitter, a social media platform. Participants were recruited using non-probability convenience sampling that included a combination of volunteer and snowball sampling (i.e., participants could refer other participants to the program). Although nonprobability sampling can introduce self-selection bias, it was the most cost-effective and feasible method of sampling participants for this pilot study. More importantly, as a person-centred behavioural change intervention, as with any successful behaviour change program, a certain level of motivation is required to participate. Due to the pilot nature of this study, no formal sample size calculations were done. The sample size of N=30 was chosen based on resources and is considered conventional for pilot studies as it permits the collection of sufficient data while minimizing research costs.[42] Additionally, studies suggest that small group sizes (≤15 participants per group) are ideal when delivering health-related, behavioural change interventions for illness prevention and self-management programs.[43]

All healthcare providers in the intervention arm (family physician, dietician and musculoskeletal specialist) and the research assistant delivering the comparator group (henceforth, interventionists unless otherwise specified) (N=4), and participants' primary

healthcare providers outside of the HLP (henceforth, healthcare providers) (N=17) were invited to participate in semi-structured interviews at 6 and 12 months to explore their perspectives regarding the implementation of the HLP or the comparator intervention. All 17 participant's healthcare providers (10 from the intervention group and 7 from the comparator intervention) were invited to participate in a semi-structured interview by a faxed letter and then contacted by telephone. Healthcare providers who agreed to participate were included in the study. All HLP participants were asked if they had family members who would be interested in participating in focus groups. Participants identified family members who were then invited by the research assistant to participate in focus groups at 9 months to explore their perspectives of the HLP. Agreeing participants were then provided with information and consent forms for their family members to complete and return to the research team. Only family members who provided consent were contacted.

Randomization, Sequence Generation

Participants were randomly allocated to either the intervention or comparator group by a research assistant who had not previously met any of the participants and was not involved in recruitment or program delivery. Each participant was provided with a 6-digit identification number using the RAND function in Microsoft Excel and then randomly allocated to either group in a one-to-one ratio. The research assistant made exceptions to this randomization procedure if two or more participants knew each other prior to program enrollment (participants were asked if they knew anyone else who was participating in the study after informed consent was obtained and prior to randomization), in which case they were allocated in the same group based on the allocation of the participant with the lowest 6-digit identification number. This was to minimize the likelihood of cross-contamination between study groups. The research assistant

then notified participants of their allocation and 6-digit identification numbers were used to blind collection and the analysis process.

Intervention Procedures: Intervention group

Intervention group participants (n=15) met individually with the intervention team to develop and update their personalized healthcare goals and action plans, identify potential facilitators and barriers to their goals, and discuss various health behaviour strategies specific to their needs. These individual sessions occurred on a monthly basis. Interventionists consisted of a family physician trained in CBT, a dietician, an orthopedic surgeon, and physiotherapy students. The program was designed to allow interventionists to regularly meet and discuss or debrief on each participant's diagnoses, treatment, healthcare goals and action plans. These sessions generally occurred on a monthly basis once each participant completed their one-to-one sessions. Physiotherapy students were only involved in the intervention group's initial individual sessions to determine their potential role in the program. Participants were otherwise encouraged to continue with their usual care as recommended by their family physician and healthcare specialists.

Additionally, intervention participants were invited to attend weekly one-hour group psycho-educational health and wellness learning sessions facilitated by the family physician trained in CBT (i.e., interventionist). These psycho-educational group sessions consisted of didactic learning, workshop presentations and open discussions regarding a variety of topics related to health behaviour theories and cognitive behaviour therapy to promote lifestyle changes (see appendix B for a list of topics). These sessions were designed to provide a space for social interaction whereby participants gained a level of peer-support.[35] In total, 50 weekly sessions were pre-planned with the flexibility to adjust session topics by the interventionists to meet the

needs of participants. However, attendance in these sessions was not mandatory, allowing participants the flexibility to attend as many sessions as they would like as would happen in real-world settings. After completing the program, participants took part in a group graduation ceremony and received a certificate of completion.

Intervention Procedures: Comparator group

In the comparator group, participants met with a research assistant once every three months for approximately one hour. The research assistant was trained in health behaviour theories by taking a graduate course at McMaster University. Similar to the intervention group, participants in the comparator group met individually with the research assistant to develop and update their personalized healthcare goals and action plans, identify potential facilitators and barriers to their goals, and discuss various health behaviour strategies specific to their needs. These sessions were provided in person with the option to meet by phone to accommodate scheduling conflicts. Participants were encouraged to continue their usual care as recommended by their family physician and healthcare specialists. There were no group psycho-educational health and wellness sessions offered to participants in the comparator group. All participants received a certificate on completion of the program but there was no group graduate ceremony.

Data Collection

Data collection occurred between January 2018 to May 2019.

Quantitative Data Collection

Participant data collection occurred at baseline and subsequently at every 3-month interval for 12 months totaling five collection time-points. See appendix C for a summary of measures and timeline of data collection. Demographic information, lifestyle factors (smoking and alcohol use) and Physical Activity Readiness Questionnaire (PAR-Q+) were collected only

at baseline for screening and assessment purposes. Interventionists had access to all participant data at baseline to inform appropriate goals, specifically, the PAR-Q+ information helped interventionists develop appropriate goals related to physical activity in alignment with participants' health status. Quantitative data were collected using the Research Electronic Data Capture (REDCap) tool, a secure research database. Participants used tablets to answer surveys and questionnaires that directly stored their data onto REDCap. Goal and anthropometric measures were collected in-person and entered into REDCap by research assistants. Feasibility measures including recruitment, participation and retention rates, missing data, and attendance rates for program was collected by the interventionists and recorded in Excel and REDCap.

Qualitative Data Collection

Qualitative data were collected using semi-structured interviews with participants from both groups at 12-months, and with interventionists and healthcare providers at 6 and 12-months. Qualitative data were also collected from family members of participants using focus groups at 9-months. All interviews were conducted by research assistants not involved with program delivery using a semi-structured interview guide (see appendix D). The interview guides consisted of open-ended questions with probes to direct the interview while allowing participants to speak freely about the HLP and for facilitators to ask additional follow-up questions. All interviews were audio recorded and transcribed verbatim, and notes were taken during the interviews. Interviews occurred in closed office or classroom settings to ensure privacy, either at David Braley Health Sciences Centre, McMaster University, or at the healthcare provider's clinic in Hamilton, Canada.

Primary outcome measures: Feasibility

The first objective was to assess the feasibility of the HLP intervention. It was measured as recruitment, participation and retention rates, missing data, and attendance rates for program components. Participation rate was operationally defined as the percent of participants who commenced the program after allocation, and retention rates as the percent of participants who completed the program at 12-months after allocation.

Implementation factors

The second objective was to evaluate the implementation factors relating to the HLP using the RE-AIM framework.[44,45] This evaluation-implementation hybrid framework was designed to translate evidence into practice, especially in the context of scaling pragmatic studies carried out in real world, complex settings.[46] The RE-AIM framework has an unique focus on internal and external validity, including process measures designed to capture intervention context, setting, and various implementation factors.[46,47] The RE-AIM framework has been frequently applied in public health and health behaviour change research with over 2,800 citations, illustrating its applicability across different study populations, settings, and health conditions.[46,47] It is useful to determine the impact of a health intervention at the individual and setting level, helping program planners and evaluators systematically focus on identifying contextual and setting factors that may have implications on program delivery in pragmatic settings.[4849]

There are five domains to the RE-AIM framework that are monitored and evaluated, this includes the reach (R) of the intervention to the target population and representativeness of the target population; the effectiveness (E) of the intervention to induce change in relevant outcomes; the adoption (A) of the intervention by those responsible for implementing the intervention; the implementation (I) factors during the delivery of the intervention including

consistency, cost, and adaptations and; the maintenance (M) of the intervention or sustainability of the intervention including the impact and factors related to the ability to incorporate into routine practice.[50]

Reach

Reach was assessed by descriptively analyzing participant baseline demographic characteristics and self-reported prevalence of modifiable risk behaviours, chronic diseases and multimorbidity. Demographic characteristics included age, marital status, educational level, employment status, and household income. Modifiable risk behaviours included tobacco use, recreational drug use, problematic alcohol consumption, low physical activity, overweight and obese. According to Public Health Ontario[51], problematic alcohol consumption was defined as more than two drinks per sitting for females or three or more drinks per sitting for males. Low physical activity was defined by Public Health Ontario as less than 150 minutes of activity per week.[51] Overweight was defined as a Body Mass Index (BMI) of 25-30 and obese was defined as a BMI of 30 or higher. [51] Multimorbidity was defined as two or more self-reported chronic conditions. Reach outcomes were compared descriptively to Hamilton, Canada, census data[52] and Public Health Ontario's[51] health data to assess representativeness.

Effectiveness

Effectiveness was assessed by analyzing the following outcomes for both the intervention and comparator groups and was collected at baseline, 3, 6, 9 and 12 months:

Mean number of goals was a descriptive measure of the average number of goals each participant was actively working towards addressing.

Goal Attainment (GA) scores were measured by participants indicating their level of attainment on a 7-point Likert scale, with 1 representing the 'worst case', 7 representing the 'best

case', and 4 representing somewhere in the middle. Each scale was personalized and developed based on the participant's baseline for that goal, ability, motivation, and purpose for the goal following a method developed for this program. Mean GA was calculated exclusively from goals created at baseline and sustained through to the 12-month period. It was decided a priori to analyze data per protocol analysis, therefore, goals developed after baseline or dropped prior to completing the 12-month study were excluded from the mean goal attainment analysis. [35] This ensures that the variation of time spent on goals and time enrolled in the study is controlled when calculating the mean GA scores for each timepoint. [53] There is no published minimal clinically important difference (MCID) for GA scores, however, we decided a priori that a change of 1 point was clinically important as each scale measured behaviours that were participant-relevant and each point was defined. [35]

Anthropometric data included participant's BMI, systolic blood pressure, diastolic blood pressure, waist circumference, hip circumference, and waist-hip ratio. The MCID for BMI is a 5 to 10% reduction from baseline[54] and for blood pressure is a 2mmHg reduction.[55] There are no published minimal clinically important differences for waist circumference, hip circumference, and waist-hip ratio.

Mental health and health-related quality of life scales

Depression was measured through the use of the Patient Health Questionaire-9 (PHQ-9), a validated 9-item questionnaire screening tool in the general population setting.[56] PHQ-9 assesses depression severity as a continuous measure that is translated to categorical diagnostic groups, whereby threshold scores of 5, 10, 15, and 20 correlate with mild, moderate, moderately severe, and severe depression, respectively.[57,58] Depression scores greater than 10 (moderate depression) have a sensitivity of 0.80 (95% CI 0.71–0.87) and a specificity of 0.92 (95% CI

0.88–0.95). [59] The positive likelihood ratio is 10.12 (95% CI 6.52–15.67) and the negative likelihood ratio is 0.22 (0.15 to 0.32).[59] The minimal clinically important difference for PHQ-9 is a 5-point change.[60,61]

Anxiety was measured through the General Anxiety Disorder 7-item scale (GAD-7), a validated tool for screening and measuring severity of anxiety in clinical and research practices. [62] The GAD-7 measures anxiety using seven items that are scored from zero to three, the entire scale ranges from 0 to 21. The cut-offs for mild, moderate and severe anxiety are 5, 10, and 15 respectively. [62] At the cut-off score of 10, both sensitivity and specificity have been shown to be greater than 0.8 and self-reported versions of the scale have been shown to be reliable compared to interviewer-administered versions. [62] However, GAD-7 scores were excluded from the analysis due to implementation limitations described in the discussion section.

Insomnia was measured with the Insomnia Severity Index (ISI), a 7-item self-reported questionnaire assessing participants' perceptions regarding the nature, severity, and impact of insomnia in the past month. The ISI is a brief and validated instrument that measures insomnia according to criteria from the International Classification of Sleep Disorders and the DSM-IV. [63,64] ISI is a continuous measure that translates to categorical diagnostic groups whereby scores from 0-7 represent no clinically significant insomnia, scores of 8-14 represent the subthreshold for insomnia, scores of 15-21 represent moderately severe clinical insomnia, and scores of 22-28 are classified as severe clinical insomnia. [65] The MCID for ISI has been reported to be a 6-point reduction in score, which is associated with a lower likelihood of the participant reporting being *worn out* or *fatigued.* [66] Morin et al. reported that a change in ISI score of ≥8 corresponded with a clinical rating of *moderate* improvement in patients receiving treatment for insomnia, and a change of ≥9 corresponded with *marked* clinical improvement.[65] However, Vitiello et al.

documented that a ≥ 30% of the original baseline ISI score was clinically significant in their cognitive behavioural study. [67]

Stress was measured using the Life Change Index Scale (LCIS) and Perceived Stress Scale (PSS). The LCIS, also known as the Holmes and Rahe stress scale, measured cumulative weighted points based on life events. It has been shown that higher scores are associated with increased medical utilization in primary care settings.[68] The LCIS is a validated measure of life events or stressors which are ranked and correlated to the probability of developing a stress related illness.[69] Although this scale was originally developed using medical records of 5000 male patients in the Unites States in 1967, it was later assessed for cross-cultural validity against African and Mexican populations in the United States as well as populations from Denmark, Sweden, Japan and Malaysia.[70–73] This scale has been shown to be consistent amongst populations despite differences in age, gender, race, religion, cultures and patient populations (vs. general population).[69] The scale lists 43 common stressful life events. Scores less than 150 indicate a low level of stress and a low likelihood of developing a stress related illness (i.e., 30% chance of illness). Scores ranging from 150 to 299 are associated with a moderate or 50% risk of developing a stress related illness. Scores greater than 300 are associated with a high risk or an 80% chance of developing stress related illness in the next two years. The Perceived Stress Scale (PSS) is a self-reported tool used to measure the degree to which participants perceived their level of psychological stress. [74] The PSS assesses stress through items that are perceived as being generally unpredictable, uncontrollable, and overloading during the previous month rather than measuring stress through specific life events and/or experiences as observed with the life change index scale. [75] The 10-item (PSS-10) scale was used rather than the original 14-item scale because it is shorter and easier to administer with psychometric properties evaluated to

have superior test-retest reliability and validity than the 14-item scale. The PSS 4-item scale is recognized as the least effective tool; however, it is the most feasible and useful tool where short questionnaires are preferred. It was included in the study to explore its feasibility against the PSS-10 for a larger definitive trial.[74]

Health related quality of life was measured using the RAND Short Form 36 (SF-36) and the Health Utility Index Mark 2 (HUI2) and Health Utility Index Mark 3 (HUI3) in order to determine which instrument would be most responsive or relevant for a larger trial. The SF-36 is a validated instrument created from the Medical Outcomes Study, a four-year longitudinal study that incorporated patient's point of view to assess healthcare outcomes.[76] The SF-36 measures eight domains related to quality of life: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health. The SF-36 has been shown to be reliable across many medical conditions including pulmonary, cardiac, endocrine, renal, and orthopedic disorders.[76] Scoring for each SF-36 domain is weighted and transformed into a scale from 0, representing the worst possible health/ severe disability, to 100, representing the best possible health/ no disability. The scores from the eight domains are aggregated to provide a Physical Component Summary (PCS) score and a Mental Component Summary (MCS) score. As described by Ware and Kosinski, the component scores are reported and analyzed in addition to the domain scores in order to make conclusions. [77] The MCID for the SF-36 is 2-points for PCS, 3-points for MCS and 2 to 4-points for each domain. [78,79]

HUI2 and HUI3 are validated tools used to measure health status and health-related quality of life. [80] In the HUI2, health-related quality of life is characterized by six attributes: sensation (vision, hearing, and speech), mobility, emotion, cognition, self-care, and pain. The

overall utility scores for HUI2 ranges from -0.03 to 1.0, with -0.03 representing a health state worse than death, 0.0 representing death, and 1.0 representing perfect health. [80] In HUI3, health-related quality of life is characterized by eight attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain. The overall utility scores for HUI3 ranges from -0.36 to 1.0, where -.36 represents a health state worse than death, 0.0 representing death, and 1.0 representing perfect health. [80] When analyzing health utility scores, it is recommended to use both the overall summary scores as well as the single-attribute utility scores. The multi-attribute health utility scores provide a single aggregate measure to capture health-related quality life, and the single-attribute scores provide supplementary information to help identify attributes causing poor health-related quality of life. [80] The MCID for HUI2 and HUI3's multi-attribute scores are 0.03 and for the single attribute scores are 0.05. [81]

Loneliness is a subjective indicator of social well-being, however, despite its social context, it is a measure of distress from feeling alone or separated. Studies have shown a link between loneliness and health outcomes including mortality and morbidity. [82] Furthermore, loneliness has been linked to personality disorders, psychoses, suicide, impaired cognitive performance, cognitive decline, Alzheimer's, depression, perceived stress, anxiety, and diminished optimism and self-esteem. [82] Loneliness was measured using the DeJong Gierveld Loneliness Scale (DJGLS) short form, a 6-item questionnaire that contains two subscales, three items are indicators for social loneliness and three items are indicators for emotional loneliness.[83] The total loneliness scale ranges from 0, not lonely, to 6, extremely lonely. Emotional loneliness scores range from 0, not emotionally lonely, to 3, intensely emotionally lonely. Similarly, the social loneliness score ranges from 0, not socially lonely, to 3, intensely socially lonely. The DJGLS has been shown to be valid and reliable as a measure of loneliness among older adults,

especially within Canadian populations (Cronbach's alpha was 0.64 to 0.74). [84] The response options for each item of the DJLS includes 'Yes', 'More or less', and 'No', and is scored dichotomously assigning a value of 1 to the neutral and positive responses for the three negatively worded items. Subsequently, a value of 1 is assigned to the neutral and negative responses for the three positively worded items. However, we modified the scoring of responses to maximize the scale's sensitivity to measure change by assigning a value of 2 to 'Yes', 1 to 'More or less' and 0 to 'No' for the positively worded items, and a value of 2 to 'No', 1 to 'More or less' and 0 to 'Yes' for the negatively worded items, changing the total scoring system from 6 to a 12-point scale [85] There are no published minimally important clinical differences for the DJGLS.

Satisfaction, enjoyability and *usefulness of the interventions* were measured at 3, 6, and 9-months using 5-point Likert questions. These outcomes were measured for continuous quality improvement purposes and 9-month scores were analyzed to assess overall participant satisfaction, enjoyability and usefulness. Participants in both groups were asked to rate their level of satisfaction, enjoyability and usefulness of the program from very satisfied/enjoyable/useful (5), somewhat satisfied /enjoyable/useful (4), neutral (3), Not very satisfied /enjoyable/useful (2), and not at all satisfied /enjoyable/useful (1). In addition, qualitative, semi-structured interviews were conducted with participants at 12-months to provide context regarding any quantitative findings regarding satisfaction, enjoyability and usefulness.

A costs and medical utilization log was provided to participants to self-report their direct costs and medical utilization every three months at the 3, 6, 9, and 12-month data collection periods. The costs and medical utilization log can be provided by request.

Adoption

Adoption outcomes were assessed using qualitative data collected from semi-structured interviews at 6 and 12 months with interventionists and healthcare providers to understand why they would participate in the delivery of or refer patients to the HLP.

Implementation

Implementation factors relating to the HLP were assessed using qualitative data collected from participants, family members and interventionists to explore their perspectives of components of the program that were implemented as planned, worked well or could be improved.

Data Analysis

Quantitative Data Analysis

Demographic and feasibility outcomes were analyzed descriptively and reported as counts or percentages when appropriate. To analyze changes in outcomes, generalized estimating equations (GEE) were used to estimate the average treatment effects within and between groups for each outcome. The purpose of the within-group analysis was to explore outcome trends over time. Therefore, GEE analyses were used that incorporated data from all 5 time-points of the study (baseline, 3, 6, 9,12-months) to estimate the change over time within either the intervention or comparison group. For the between group analyses, the purpose was to explore differences between groups at the 12-month period. Therefore, this GEE analysis used the difference between baseline and 12-month responses to control for baseline variation in the outcome data. Additionally, a GEE analysis was used to analyze the correlation between attendance to group sessions in the intervention group and participant-centered outcomes. With the exception of the attendance and outcome analysis, all other GEE analysis controlled for gender and age, which was decided a priori. [35] Other covariates were excluded from the analysis due to the exploratory

nature of this pilot study and its small sample size. The identity link function was used for all outcomes, and the autoregressive correlation structure was used because it accounts for the longitudinal design where measurements closer in time are more closely correlated than those further apart. A *p* value of less than 0.05 was considered statistically significant. All quantitative data were analyzed using SPSSv27.

Qualitative Data Analysis

All interviews were audio recorded then transcribed verbatim and entered into NVivo12. Transcripts and notes were initially read in full to gain an overall understanding of the data. Transcripts and notes were coded line by line and the coded segments were grouped into common concepts and themes guided by the RE-AIM framework. Themes were developed using inductive thematic analysis with a realist approach to interpreting the data.[86,87] Data analysis occurred through a multi-stage process where the author became familiarized himself with the data, generated initial codes, confirmed codes with the Principal Investigator, developed themes, discussed and confirmed themes with the Principal Investigator , and then conducted the write up of the analysis.[87] Any discrepancies or clarifications were discussed until a consensus was reached. Qualitative data were used to enrich quantitative findings, to understand implementation factors, and enhance future iterations of the HLP.

Ethics

This study was approved by the Hamilton Integrated Research Ethics Board (HiREB; #3793) and registered with ClinicalTrials.gov (identifier: NCT03258138).

RESULTS

Primary Objective: Feasibility

Recruitment

Recruitment began January 2018 and ended March 2018. Figure 2 illustrates the CONSORT diagram for participant flow through the study. Of the 72 individuals who contacted the program, 31 attended an information session and signed consent to participate. During the consent process, one participant was excluded from the study because of untreated and unstable mental health issues disclosed to the Principal Investigator during the informed consent process. This was not an explicit exclusion criterion at the time, but was necessary due to potential for adverse outcomes to the group. As randomization had not yet occurred, one additional participant was recruited to meet the sample size of 30. Therefore, 97% (30/31) of participants invited to the study were eligible for enrollment.

Participant feedback surveys at three months follow-up (N=16) collected data on recruitment sources (i.e., *how did you find out about the healthy lifestyles program? list up to three)* and reasons for enrollment (i.e., *what made you want to join the program?*). Sources of recruitment were from local newsletter advertisements (n=8, 42%), word of mouth (n=6, 32%), and posters (n=5, 26%). Reasons for participant enrollment included seeking support to improve general health or lifestyle (n=12, 63%), physical health or weight loss (n=6, 32%), nutrition or healthy eating (n=2, 11%), mental health (n=1, 5%), and pain management (n=1, 5%).

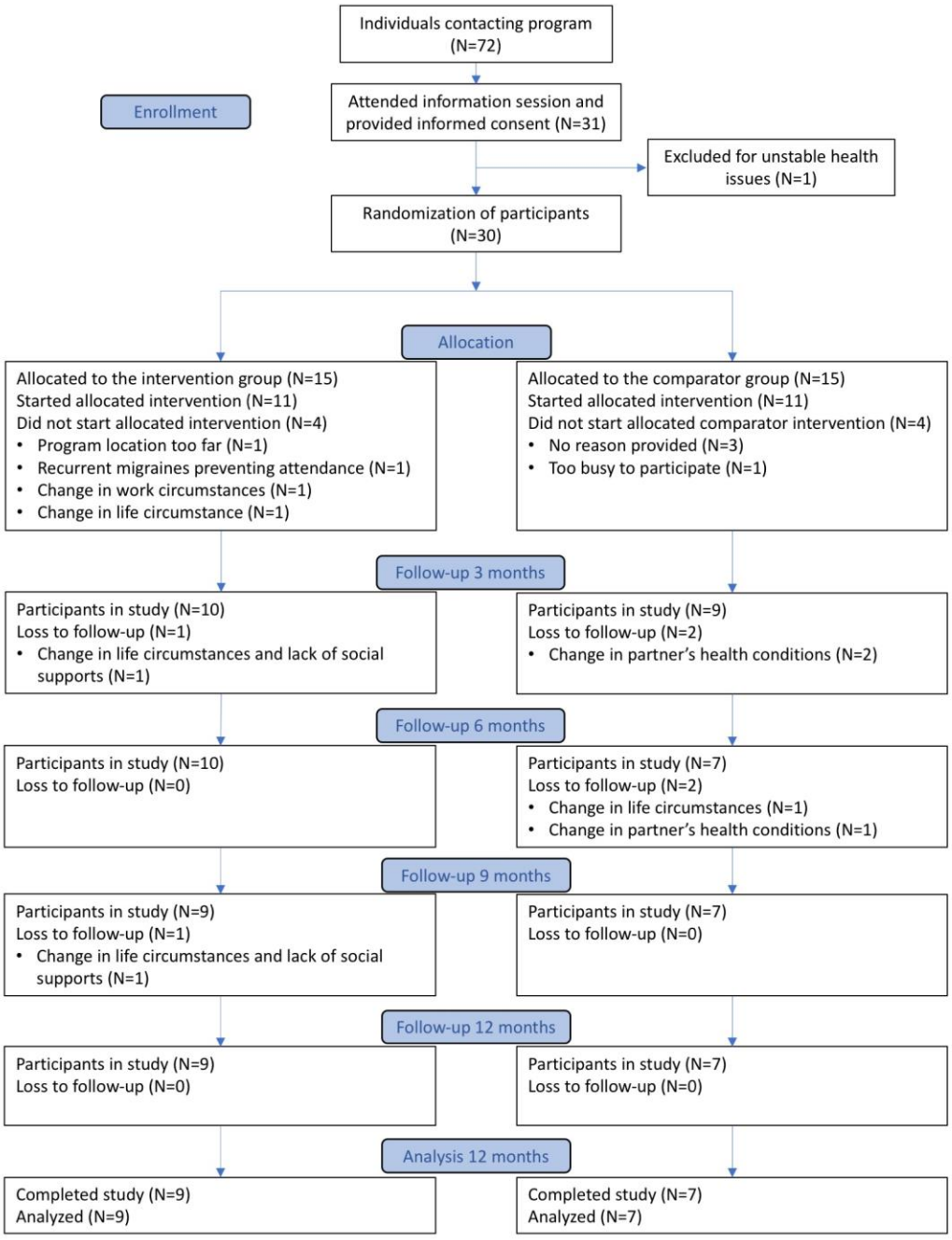

Fig. 2 Consort flow chart.

Participation and retention rates

The HLP began in April 2018 and ended in April 2019. The study participation rate was 73% (22/30), participation rates were even between the intervention (11/15) and comparator

(11/15) groups, see figure 2. The overall study retention rate after 12-months was 53% (16/30); 60% (9/15) for the intervention group and 47% (7/15) for the comparator group. There were no moderate to severe adverse events related to the study.

Missing data

Less than 1% of the self-reported mental health and anthropometric data were missing for participants who completed the study after 12-months. There were no missing data for goal attainment scores. Costs and medical utilization logs were piloted and missing data among the intervention participants were 31% and 60% for the comparator participants. GAD-7 (anxiety) data were consistently collected as a result of technical settings in REDcap.

Attendance to program components

For participants who completed the study, there was 100% attendance to the individualized portions of the program in both the intervention and comparator groups. Over 50 weeks, 43 educational sessions were delivered to participants in the intervention group. Participants in the intervention group who completed the study (n=9) attended an average of 29 (SD=7.5) weekly sessions and the range was from 15 to 38 sessions. The overall average number of participants per session was 6 (SD= 1.8). Average attendance decreased over time; attendance rate was the highest in the first three months with an average of 84% and lowest in the last three months of the program with an average of 43%.

Secondary Objective: Implementation

Reach

Table 1 summarizes baseline characteristics of participants. Four participants in the comparator group dropped out of the program after allocation and prior to collecting demographic data. Baseline data was collected after randomization at the beginning of the

program to avoid overburdening the information, consent and intake process for participants. There were no statistically significant differences in demographic characteristics between participants randomized to the intervention and comparator groups. In comparison to the 2016 Hamilton census data, the program recruited a study sample of participants who were older, predominately women, more highly educated and less likely to work either full-time or part-time. Participants exhibited greater prevalence of modifiable risk factors and chronic diseases than observed in the general adult population of Hamilton, Ontario.

Table 1. Demographic and health characteristics of participants (N=26). Hamilton, Ontario, population data sourced from Statistics Canada and 2015-16 Hamilton data sourced from Public Health Ontario.[51,52]

	All participants	**Intervention**	**Comparator***	**Hamilton Population**
Total n (%)	26 (100)	15 (57)	11 (43)	536,917
Mean age in years (SD)	54.31 (12.93)	57.87 (11.72)	49.45 (13.45)	41.3
Gender, n (%)				
Female	21(80.7)	12 (80)	9 (81)	(54.5)
Male	5 (19.3)	3 (20)	2 (19)	(45.5)
Marital Status, n (%)				
Common Law	3 (11.5)	1 (7)	2 (19)	(8.5)
Divorced	4 (15.5)	2 (13)	2 (19)	(6.4)
Married	10 (38.5)	7 (47)	3 (25)	(46.4)
Other Partner	3 (11.5)	1 (7)	2 (19)	NA
Single	3 (11.5)	2 (13)	1 (9)	(32.4)
Widowed	3 (11.5)	2 (13)	1 (9)	(6.2)
Education level, n (%)				
< High School	1 (4)	0	1 (9)	(17.8)
High School	2 (8)	2 (13)	0	(27.8)
College	15 (58)	8 (53)	7 (63)	(22.8)
Bachelor's	5 (19.5)	4 (27)	1 (9)	(15.5)
Master's	3 (11.5)	1 (7)	2 (19)	(4.4)
Employment status, n (%)				
Full-time or part-time	12 (46)	6 (40)	6 (56)	(60.2)
Disability or sick leave	5 (19.5)	3 (20)	2 (19)	NA
Retired	8 (30.5)	5 (30)	3 (25)	NA
Other	1 (2)	1 (7)		NA
Household Income, n (%)				
<$20,000	3 (11.5)	1 (7)	2 (19)	(8.4)
$20,000 to 50,000	8 (30.5)	5 (30)	3 (25)	(23.6)
$50,001 to 80,000	5 (19.5)	3 (20)	2 (19)	(20.8)
$80,001 to 120, 000	5 (19.5)	2 (13)	3 (25)	(22.3)
>$120,000	4 (15.5)	4 (27)	0	(24.9)
Refused	1 (4)	0	1 (9)	NA
				% (95%CI)
Modifiable Risk Behaviours, n (%)				

Current Tobacco User	2 (8)	0	2 (19)	15.3 (12.2-18.4)
Recreational Drug Use	5 (19)	1 (7)	4 (36)	0.09 (0.08-0.099)
Problematic Alcohol Consumption**	8 (31)	6 (40)	2 (19)	19.9 (16.6-23.2)
Low Physical Activity***	15 (52)	9 (60)	6 (56)	22.4 (18.4-26.4)
Overweight+	7 (27)	2 (13)	5 (45)	21.2 (16.9-25.6)
Obese+	17 (65)	11(73)	6 (56)	34.1 (29.7-38.5)
Chronic Diseases, n (%)				
Anxiety	13 (50)	5 (33)	8 (73)	11 (8.3-13.7)
Diabetes Type 2	3 (11.5)	2 (13)	1 (9)	7.1 (5.1-9.1)
Heart disease	0	0	0	4.5 (3.0-6.1)
High blood pressure	6 (23)	4 (27)	2 (19)	20.5 (17.7 – 23.2)
Stroke	1 (4)	0	1 (9)	1.0 (0.3-1.6)
Multimorbidity, n (%)	21 (80.7)	12 (80)	9 (81.8)	24.3

SD = Standard Deviation, NA= Not Available, CI= Confidence Interval
Percentages may not add up to 100% due to rounding
*Missing data (N=4) in comparator group as loss to follow-up before baseline data collection
** Defined as more than 2 drinks per sitting for females or 3 drinks per sitting for males
*** Defined as below the recommended level of 150 minutes of physical activity per week

Effectiveness

Within-group analyses

A GEE analysis was conducted to identify changes in outcomes within each group over the 12-month study period and controlling for age and gender. The results of the within-group analysis are summarized in table 2 for participants in both the intervention (n=9) and comparator (n=7) groups. Among participants in the intervention group, there were statistically significant improvements in mean scores for insomnia, depression, stress (in both the 4 and 10 item scales), loneliness, number of active goals, goal attainment, and health-related quality of life indicators in the RAND SF-36 for pain, general health and physical composite scores over 12-months. Additionally, there was a small but significant decrease in waist to hip ratio over 12-months. Among participants in the comparator group, there were small but statistically significant improvements in mean scores for insomnia, perceived stress (in the 10 but not the 4-item scale), number of active goals, goal attainment, and RAND SF-36 general health scores over the 12-months. However, the effect estimates for these outcomes were lower than the MCID.

Table 2. Within-group analysis of outcomes for participants in the intervention group (n=9) and comparator group (n=7) using GEE. Analysis controls for gender and age. P values <0.05 are significant.

Outcome	Intervention Group				Comparator Group				MCID
	Baseline	12-months	Change	p-Value	Baseline	12-months	Change	p-Value	
	Mean (SD)	Mean (SD)	β (95%CI)		Mean (SD)	Mean (SD)	β (95%CI)		
Mental Health									
Insomnia Severity Index (ISI)	9.56 (5.00)	5.33 (4.92)	-1.19 (-2.04 to -0.33)	0.006	9.71 (4.39)	8.00 (3.51)	-0.45 (-0.81 to -0.09)	0.014	6
Patient Health Questionnaire 9	7.56 (5.27)	3.00 (1.73)	-1.01 (-1.76 to -0.27)	0.008	6.7 (4.72)	5.43 (2.99)	-0.27 (-0.86 to 0.33)	0.384	5
Perceived Stress Index – 4 Item (PSS4)	5.44 (3.00)	2.56 (1.13)	-0.670 (-1.12 to -0.22)	0.003	5.43 (3.15)	4.29 (1.89)	-0.25 (-0.69 to 0.19)	0.257	ND
Perceived Stress Index – 10 Item (PSS10)	14.89 (5.82)	8.67 (3.74)	-1.44 (-2.31 to -0.57)	0.001	14.57 (5.68)	11.14 (4.74)	-1.00 (-1.75 to -0.25)	0.009	2 to 4
Life Change Index (LCI)	290 (245)	217 (131)	-16.87 (-67.884 to 32.15)	0.517	501 (506)	446 (331)	-11.12 (-32.45 to 10.22)	0.307	ND
DeJong Gierveld Total Score (loneliness)	3.22 (2.82)	0.56 (0.88)	-0.48 (-0.76 to -0.21)	<0.001	3.00 (3.92)	2.43 (2.99)	-0.14 (-0.40 to 0.12)	0.279	ND
Goals									
Number of Active Goals	2.67 (0.71)	3.67 (1.12)	0.20 (0.07 to 0.02)	0.003	1.71 (0.49)	2.57 (0.79)	0.21 (0.10 to 0.33)	<0.001	ND
Goal Attainment Score	1.81 (0.60)	5.40 (0.96)	1.06 (0.89 to 1.23)	<0.001	2.07 (1.10)	4.21 (0.99)	0.59 (0.35 to 0.84)	<0.001	1
Rand SF-36 (health related quality of life)									
Physical Functioning	48.33 (31.22)	58.33 (34.00)	2.48 (-2.31 to 7.27)	0.310	67.14 (28.12)	75.00 (19.79)	1.96 (-0.73 to 4.65)	0.154	10
Role Limitation due to Physical Health	36.11 (48.59)	52.77 (40.40)	5.02 (-1.67 to 11.71)	0.142	46.43 (44.32)	60.71 (49.70)	3.05 (-5.78 to 11.88)	0.498	10
Role Limitation to due Emotional Well-Being	48.15 (44.44)	55.56(37.27)	1.85 (-0.91 to 4.62)	0.189	61.90 (40.50)	57.14 (41.79)	-0.02 (5.78 to 5.74)	0.995	10
Energy/ Fatigue	38.89 (25.59)	52.22(10.34)	3.08 (-0.66 to 6.81)	0.106	45.71 (17.66)	57.86 (18.00)	3.10 (-0.93 to 7.12)	0.131	10
Emotional Well-Being	72.44 (14.76)	79.11 (7.15)	1.13 (-0.16 to 2.41)	0.085	71.43 (20.97)	71.43 (13.15)	0.95 (-1.91 to 3.81)	0.516	10
Social Functioning	58.33 (33.66)	72.22 (19.54)	3.24 (-0.02 to 5.50)	0.051	64.29 (32.62)	71.43 (21.30)	2.36 (-1.69 to 6.41)	0.253	10
Pain	51.67 (27.39)	68.33 (27.78)	4.30 (1.52 to 7.09)	0.002	49.64 (31.83)	53.93 (24.50)	0.97 (-2.42 to 4.35)	0.575	10
General Health	35.00 (14.58)	57.22 (25.01)	5.57 (2.02 to 9.12)	0.002	57.86 (25.63)	65.71 (22.81)	1.95 (1.13 to 2.76)	<0.001	10

Physical Composite Score	34.11 (11.81)	41.72 (14.09)	1.95 (0.06 to 3.85)	0.043	40.31 (11.32)	45.27 (6.14)	1.19 (-0.22 to 2.61)	0.099	2 to 4
Mental Composite Score	42.73 (8.12)	46.63 (7.52)	0.29 (-1.60 to 2.18)	0.761	44.33 (13.58)	45.04 (11.72)	0.43 (-1.31 to 2.17)	0.630	2 to 4
Health Utility Index (health related quality of life)									
HUI3 Composite Score	0.44 (0.33)	0.59 (0.28)	0.03 (-0.01 to 0.08)	0.155	0.54 (0.28)	0.62 (0.22)	0.02 (-0.02 to 0.05)	0.373	0.03
HUI2 Composite Score	0.61 (0.29)	0.69 (0.18)	0.02 (-0.01 to 0.05)	0.250	0.67 (0.30)	0.70 (0.24)	0.01 (-0.02 to 0.03)	0.548	0.03
HUI General Health	3.78 (0.97)	3.33 (1.22)	-0.15 (-0.39 to 0.09)	0.219	2.86 (0.69)	2.57 (0.79)	-0.07 (-0.20 to 0.06)	0.285	0.05
Anthropometric									
Systolic BP (mmHG)	126.57 (9.83)	131.14 (19.12)	-19.88 (-46.97 to 7.22)	0.150	123.86 (20.47)	120.29 (18.63)	-1.24 (-2.97 to 0.48)	0.659	2
Diastolic BP (mmHG)	83.29 (9.55)	79.00 (8.45)	-24.55 (-54.10 to 5.00)	0.103	79.86 (7.65)	76.57 (10.11)	-0.90 (-2.70 to 0.89)	0.324	2
BMI (kg/m^2)	42.33 (8.52)	42.55 (7.89)	0.05 (-0.20 to 0.30)	0.667	30.04 (5.25)	30.17 (5.24)	0.03 (-0.30 to 0.37)	0.849	5 to 10%
Hip circumference (cm)	134.20 (16.89)	135. 62 (17.48)	0.36 (-0.49 to 1.20)	0.688	114.31 (7.49)	112.57 (10.31)	-0.37 (-1.32 to 0.58)	0.444	ND
Waist circumference (cm)	127.91 (21.24)	125.48 (21.27)	-0.63 (-2.03 to 0.77)	0.375	104.86 (7.58)	105.71 (7.78)	0.23 (-0.93 to 1.39)	0.695	ND
Waist-hip ratio	0.95 (0.05)	0.92 (0.07)	-0.01 (-0.02 to -0.01)	0.023	0.92 (0.05)	0.94 (0.04)	0.01 (0.001 to 0.01)	0.013	ND

ND – Not determined

Between group analyses

The overall test of the intervention effect compared to the comparator group was performed using a GEE analysis. Table 3 summarizes effect estimates after 12-months and controlling for baseline differences, age and gender. Participants in the intervention group were significantly more likely to increase their goal attainment score by 1.36 points (95%CI: 0.51, 2.20), reduce their depression score by 4.08 points (95%CI: -7.23, -0.94), reduce their loneliness scores by 2.23 points (95%CI: -3.88, -0.58), and increase their RANDSF-36 general health score by 16.92 (95%CI: 3.38, 39.47) than participants in the comparator group after 12-months. Additionally, there was a small but statistically significant intervention effect on decreasing waist to hip ratio after 12-months.

Table 3. Between group analysis for patient-centered outcomes (N=16) using GEE analysis and controlling for age and gender. P- value <0.05 are significant.

OUTCOMES (N=16) Comparator group used as reference	Effect (β)	95% CI		*p*-value
		Lower	Upper	
Mental Health				
Insomnia Severity Index	-2.48	-5.75	0.79	0.138
Patient Health Questionnaire 9	-4.08	-7.23	-0.94	0.011
Perceived Stress Index – 4 Item scale	-1.54	-4.16	1.09	0.251
Perceived Stress Index – 10 Item scale	-2.40	-7.33	2.53	0.340
Life Change Index	-28.79	-208.20	150.61	0.753
DeJong Gierveld Score	-2.23	-3.88	-0.58	0.008
Goals				
Number of Active Goals	0.12	-0.40	0.64	0.659
Goal Attainment Score	1.36	0.51	2.20	0.002
Rand SF-36				
Physical Functioning	9.41	-6.42	25.24	0.244
Role Limitation due to Physical Health	3.29	-47.24	53.83	0.898
Role Limitation to due Emotional Well-Being	11.67	-25.92	49.26	0.540
Energy/ Fatigue	0.95	-23.82	25.72	0.940
Emotional Well-Being	6.90	-3.13	16.92	0.178
Social Functioning	7.28	-10.64	25.19	0.426
Pain	14.42	-3.32	32.15	0.111
General Health	16.92	3.38	39.47	0.014
Physical Composite Score	4.17	-4.68	13.02	0.356
Mental Composite Score	3.43	-5.29	12.14	0.441
Health Utility Index				

HUI3 Composite Score	0.14	-0.04	0.31	0.132
HUI2 Composite Score	0.07	-0.06	0.20	0.285
HUI General Health	-0.29	-1.33	0.75	0.583
Anthropometric				
Systolic BP (mmHG)	-8.57	-18.85	1.53	0.096
Diastolic BP (mmHG)	-0.09	-8.21	8.03	0.983
BMI (kg/m^2)	0.06	-1.97	0.76	0.935
Hip circumference (cm)	2.02	-1.63	5.67	0.279
Waist circumference (cm)	-3.77	-10.29	2.73	0.252
Waist-hip ratio	-0.05	-0.08	-0.16	0.003

Program satisfaction: quantitative findings

Participants in the intervention group rated the intervention higher in satisfaction and usefulness than participants in the comparator group. See table 4.

Table 4. Participant satisfaction, enjoyability and usefulness scores using a 5-point Likert scale. High values correspond to favourable outcomes [5= very satisfied /enjoyable/useful, 4 = somewhat satisfied /enjoyable/useful, 3= neutral, 2= Not very satisfied /enjoyable/useful, 1= not at all satisfied/enjoyable/useful].

Scores	Intervention Group N=9 Mean (SD)	Comparator Group N=7 Mean (SD)	Mean Difference [a] (95%CI)	P value
Satisfaction	5.0 (0)	3.71 (1.11)	1.28 (0.50- 2.07)	0.004
Enjoyability	4.89 (0.33)	4.29 (1.11)	0.6 (-0.23- 1.44)	0.143
Usefulness	5.0 (0)	3.43 (1.13)	1.57 (0.77-2.37)	0.001

[a]Independent t-test

Program Satisfaction: qualitative findings

These findings were supported by the 12-month qualitative interviews with participants from both the intervention (n=9) and comparator (n=7) groups. Overwhelmingly, participants in the intervention group described the program as *excellent, helpful, valuable, and life changing* and they were *happy to have spent time in the program*. Moreover, they felt the program was self-empowering, promoted health literacy or awareness, and provided the motivation and accountability to make positive changes.

> *"I think everyone should have the opportunity to have this program… because it helps you focus on your needs and wants and how to correct the habits that*

> *you accumulated all your life that are holding you back. It just is a fabulous program with your mind, your body, the exercise, it just forms a healthier you."* Intervention Participant 1 - 12 month

> *"Last year this time I felt depressed, I was completely inactive because of pain, I was not exercising at all, I was having difficulty with stairs and getting in and out of the bathtub. I felt defeated and I felt old. And over the course of this year I felt like I was given back my life. I feel healthier, I feel stronger. I feel empowered. I feel like I have been given some very important tools. I no longer feel defeated. A big difference is in my health and my outlook. My mood, exercise and diet change have made impacts to my mental health state."* Intervention Participant 2 -12 month

In contrast, participants in the comparator group had mixed reactions regarding their overall satisfaction and usefulness of the program. Most described the program as somewhat helpful, useful, and supportive. Participants in the comparator group enjoyed developing health goals with the research assistant and described it as an easy, simple, and manageable process to identify lifestyle changes. Ultimately, they felt the program was limited in helping them make those changes. One comparator group participant stated that they would have benefited more from a more intensive program and that a limitation in their progress was the lack of interaction with the program resulting in the lack of motivation and accountability to make a change.

> *"I think the program re-enforced what I know, the need for exercise and the healthy benefits in doing that and the problems that I have. I still have difficulty pushing myself to do it… I needed more contact to stay on track and to help be accountable."* Comparator Participant 1- 12 month

> *"So, for me follow-up and support are crucial. And it is terrible to think that I can't do that for myself, but I am not good at that*." Comparator Participant 2 - 12 month

Adoption

Adoption was assessed using qualitative interviews at 6 and 12-months from interventionists (n=4) and healthcare providers (n=3) to explore their perspectives on the adoption of the program. In total 7 individuals were included in this analysis of which two were

male. The common concepts regarding adoption of the program were centered on a holistic approach to care, which aligned with their personal vision and goals, including the ability to spend time with participants/patients, providing counselling and mental health supports, and professional collaboration. The main differences between the 6-month and 12-months interviews were that the participants' primary care providers were less aware of the HLP at 6-months than at 12-months.

Holistic approach to care

Providing a holistic approach to care was an important adoption factor among interventionists as they felt that the program aligned with their personal vision, mission, and goals. Specifically, they valued the ability to address both symptoms and causes of complex health issues from multiple perspectives for participants, rather than the traditional piecemeal or silo approach they experienced in the clinical setting.

> *"It's been extremely gratifying and enjoyable working with patients [participants] in this matter where you can actually not have to focus on one thing and be able to look at the entire person and say yes you've got knee pain that keeps you up at night that causes a lot of stress in your life."* Interventionist 3- 12 month

Time with participants

The ability to provide more time and increased follow-up interactions with participants was identified as a critical component to the successful acceptance and adoption of the HLP. Interventionists and healthcare providers both identified the inability to spend time with patients as a barrier to providing care in clinical settings. Therefore, interventionists valued building personal relationships with participants and being able to provide a high-quality level of care that is afforded by a 1-year program, without the external pressures and time constraints associated with a high-volume clinical practice.

> *"It's more gratifying when I don't have to try to pump them [participants] through as numbers, or not to worry about my numbers, I don't have to worry about wait times, I don't have to worry about this I can actually do something positive as opposed to say here's a prescription for this and I'll see you again in six months and then that's about it."* Interventionist 3 – 12 month

> *"[What] struck me is how patient [centred] a program it is, that it goes on for a long time as opposed to sort of that a quick dip-in and give people some advice and set some goals and then be done. That there is follow-up and fine tuning and checking in about how things are going and that I think is realistically how people make change."* Healthcare Provider 1 – 6 month

Providing counselling and mental health supports

A common acceptability and adoption theme by interventionists and healthcare providers was regarding the program's ability to provide needed counselling and mental health supports to participants. Both interventionists and healthcare providers felt that the lack of counselling supports around evidence-based preventative care and the promotion of healthy lifestyle behaviours were key barriers to providing care in practice. Therefore, healthcare providers felt that the program's ability to provide CBT and activating patients towards healthy lifestyles were important aspects of the program that were missing in their primary care settings. The program's design to address behavioural change and provide counselling and behavioural therapy supports resonated with both interventionists and healthcare providers.

> *"The healthcare system is set up for acute problems and not for chronic long-term conditions and is not set up in a supportive way where you can have the counseling, or support system in place to say it's okay that you're feeling this way we can help you to a certain point, but a lot of the onus is on you as well and giving them the tools."* Interventionist 3- 12 month

> *"The activation piece of getting people moving and exercise and active I think as a community we don't do particularly well, and you know especially for disenfranchised people who don't have resources."* Healthcare Provider 1 – 6 month

> *"It has been very difficult to access CBT for anybody let alone psychiatric patients. Getting into behavioural change for an active lifestyle I do not think they exist unless some of my counselors do a little bit of it on the side. So, CBT*

> *would be effective for those people [patients] but I do not know how to do it. But if I could send them to someone that would be great."* Healthcare Provider 3 – 12 month

Professional communication, collaboration and support

Good communication, multidisciplinary collaboration and support from interventionists were identified as important aspects contributing to the adoption of the program. Interventionists commented that debriefings afforded them the opportunity to provide their unique input, learn from others with different skill sets, and have an additional level of professional support that they otherwise would not be exposed to in their clinical practices. Interventionists found it meaningful to collaborate and communicate with participants to develop their personalized goals and action plans, which they felt was empowering for both the participants and themselves.

> *"I value also seeing or having other health professionals see what a [removed for identification purposes] does. You don't get that in many settings. Whereas here, when we are talking, I'm being able to showcase what my role is, how I am valued, how my suggestions are valued, and how the patients improved from these suggestions or how they are incorporating."* Interventionist 2- 12 month

> *"The other big thing is it is multidisciplinary; I will see the participant and I will go through between half hour to an hour with them and then another health professional will do the same. Then when we get together and talk about the patient and, all of a sudden, we see things from different angles and then we start to tease out more of the underlying issues that are involved so then we fill in each other's gaps and work really well together. Truly talking to one another about the participant, so there is a lot of communication.*" Interventionist 3 – 6 month

Implementation

Qualitative feedback regarding program implementation factors were collected through semi-structured interviews with intervention (n=9) and comparator (n=7) participants at 12-months, interventionists (n=4) and healthcare providers (n=3) at 6 and 12 months, focus groups with family members (n=3) at 9-months, and from a participant feedback survey at 9-months

(n=16). Implementation factors were found that addressed program components, duration of program, location of program, and program resources.

Program component: Individual sessions with healthcare team

There was 100% attendance to all individual monthly sessions by participants in the intervention group. Participants highly valued the monthly in-person interaction with their healthcare team because they felt that consistent follow-ups or check-ins allowed for timely and specialized attention to address any perceived barriers in maintaining engagement towards their goals. One participant compared the program's follow-up schedule to their experience in another high-intensity service but emphasized that the specialized skills and knowledge of the interventionists and their capacity to provide tailored supports and advice had set the HLP apart. The need for tailored advice extended beyond the interventionist's knowledge of the condition; it was important for participants to build that relationship and sense of trust through consistent interaction with the interventionist who understood their health and life context to provide the appropriate level of tailored supports.

> *"Well, I liked meeting once a month with the staff [interventionists] because that kept me on track and if I had barriers or obstacles and I would let them know what they are and we would work to solving them*." Intervention Participant 4- 12 month

Similarly, participants in the comparator group attended 100% of all individual sessions with the research assistant. However, comparator group participants felt that meeting with the research assistant every three months was not enough interaction to maintain engagement towards their goals and that the research assistant was limited in their capacity to provide tailored knowledge and education.

> *"Having some kind of information in between those three-month visits that was a long time and it was kind of hard to keep up the impetus I think."* Comparator participant 2 - 12 month

Program component: Group psycho-educational sessions

Participants in the intervention group valued the group psycho-educational sessions because they felt it was an opportunity to build connections and gain support from their peers, which kept them accountable to the program. One participant stated:

> *"Building the bond with people who were in the program that was also helpful to me because some days I thought oh I did not want to go because I got busy or tired I said oh no I should go because people were counting on me and/or I would learn something."* Intervention Participant 9 - 12 month

Similarly, we observed statistically significant correlations between mental health and goal related outcomes and attendance in these sessions (see table 5). Additionally, participants found the content delivered during the sessions informative. One participant commented that it was the combination of group sessions and individualized meetings with interventionists that had the greatest impact on their ability to make a behavioural change.

> "*I feel that the most useful were the sessions because we would get handouts and we take notes and sometimes we would watch videos and staff would explain the topic in great detail so I would be able to retain the information and I had a better understanding*." Intervention Participant 4 - 12 month

> "*I think one without the other would not have been so transformational for me*." Intervention participant 3 - 12 month

Regarding the delivery of the group psycho-educational sessions, interventionists commented that group sessions could be expanded to include a variety of other topics such as nutritional education and cooking, and activities such as yoga and tai chi. However, interventionists felt it was important to review or repeat sessions to re-enforce participant

understanding and address behavioural change. In total 43 of the 50 planned (86%) sessions were delivered, with most sessions cancelled due to bad weather and with minor adjustments made to the programming schedule.

Table 5. Associations between attendance and outcomes for the intervention group participants (n=9). Analysis using GEE and p-value set to 0.05.

OUTCOMES (n=9)	Effect (β)	95% CI		*p*-value
		Lower	Upper	
Mental Health				
Insomnia Severity Index	-0.166	-0.227	-0.055	0.003
Patient Health Questionnaire 9	-0.135	-0.228	-0.42	0.004
Perceived Stress Index – 4 Item scale	-0.084	-0.146	-0.022	0.008
Perceived Stress Index – 10 Item scale	-0.187	-0.312	-0.062	0.003
Life Change Index	-2.974	-11.673	5.726	0.503
DeJong Gierveld Score	-0.075	-0.111	-0.038	<0.001
Goals				
Number of Active Goals	0.035	0.013	0.057	0.002
Goal Attainment Score	0.117	0.060	0.174	<0.001
Rand SF-36				
Physical Functioning	0.255	-0.227	0.737	0.300
Role Limitation due to Physical Health	0.322	-0.555	1.199	0.427
Role Limitation to due Emotional Well-Being	0.077	-0.393	0.548	0.747
Energy/ Fatigue	0.454	0.042	0.865	0.031
Emotional Well-Being	0.226	-0.040	0.492	0.095
Social Functioning	0.510	0.052	0.968	0.029
Pain	0.320	-0.057	0.697	0.096
General Health	0.867	0.411	1.341	<0.001
Physical Composite Score	0.201	-0.004	0.406	0.055
Mental Composite Score	0.180	0.098	0.261	<0.001
Health Utility Index				
HUI3 Composite Score	0.004	-0.002	0.010	0.243
HUI2 Composite Score	0.003	-0.001	0.007	0.188
HUI General Health	-0.020	-0.047	0.008	0.160
Anthropometric				
Systolic BP (mmHG)	0.158	-0.154	0.470	0.321
Diastolic BP (mmHG)	-0.080	-0.258	0.098	0.377
BMI (kg/m^2)	-0.012	-0.048	0.024	0.517
Hip circumference (cm)	-0.138	-0.351	0.075	0.205
Waist circumference (cm)	0.012	-0.098	0.123	0.826
Waist-hip ratio	-0.001	-0.002	0.000	0.003

Proposed program components: Family involvement and community supports

Family members and participants believed family plays an important role as a support or barrier for behaviour change. Family members viewed their role as one of providing support through encouragement, participating in the adoption of lifestyle changes and providing supports. Interventionists also expressed the need to expand the program to better engage participant's family members in order to facilitate greater adoption of lifestyle changes.

> *"I've been joining in activities and supportive in terms of encouraging more consistency. I do the driving so I'm supplying the transportation.*" Family member 2 - 9 month

> "*I would think the number one thing [about family] is that if they are not participating then they are not contributing. For example, I have been trying to make food changes in what I eat, but my father is not in a position where he wants to change anything that he eats. So, I think if everyone in the house is trying to do the same then there is more of a buy-in*." Comparator Participant 4 - 12 month

Interventionists identified the need for the HLP to link participants to more community supports. Perspectives regarding the role of the community in leading a healthy lifestyle were mixed among participants. Some identified the need for greater linkage to community resources or supports, while others did not feel they needed to engage in community supports or were unaware of the supports available to them. However, participants did feel that there should be greater physically and financially accessible community supports.

> *"I think there should be more help out there for people with lower income to be able to get physio and that, because I'm having difficulty getting physio that I need and being able to pay for it.*" Intervention Participant 6 – 12 month

Proposed program component: Physical activity or exercise

The desire to have a facility or space with the capacity to provide a gym, aqua therapy or physiotherapy was highlighted by both interventionists and participants. Interventionists felt that

an on-site recreational or exercise space would better address the physical health related goals and needs for this study population to apply physical activity through practice.

> *I think it would be great to have a location like a gym or physiotherapy where we could actually make use…so that they'll be more connection between what we're recommending and what they're ultimately doing."* Interventionist 1 - 12 month

> "*The only thing that is lacking is exercise, actual physical doing exercise*." Intervention Participant 5 - 12 month

Duration of program

Participants and interventionists felt that one year or more was an appropriate duration for the program. There was recognition that behavioural change is difficult, requires time, and seldom occurs in a linear manner. Participants felt that although health goals may be achieved within the year, it can fluctuate, and having the opportunity to work on sustaining goals was important. Seasonal fluctuations, especially winter months, can be barriers to making lifestyle changes. Planning proactively for winter was addressed in the program.

> *"I think a year is really good because it is enough time that a person can experience taking steps forward and sliding back and forward again."* Interventionist 4 -12 month

> *"So, the one was weather or seasons, because I know I am affected with seasonal disorder. Certainly, when it is dark I do not do anything and I want to eat more or sleep more."* Comparator Participant 1 -12 month

> *"Yeah, I like the length of it. It was ongoing so you had your chances. I had my ups and downs and it was long winter and it was hard on everybody."* Intervention Participant 7 -12 month

Location of program

An important setting level consideration that facilitated the implementation of the program was ensuring a space that was centrally located, accessible by public transit, included parking and could accommodate individuals with mobility limitations. Having a mixture of both class-room style spaces and private consultation rooms helped facilitate the group psycho-

educational sessions, as well as created a safe and private space for interventionists and participants to discuss health goals and action plans.

> *"I love the location because it was accessible, like where we get dropped off it was all level and the fact there are elevators and accessible washrooms. The fact that the room, the chairs were accessible and were not constricting."* Intervention Participant 4 - 12 month

Program resources: Musculoskeletal (MSK) specialist and Program administrator

Having a musculoskeletal specialist allowed for accurate diagnosis and treatment of physical and mobility related issues that would have otherwise gone untreated for this particular study population.

> *"There's a huge gap in our healthcare system that does not address MSK problems. Family doctors are notoriously bad at diagnosing MSK problems and physical therapists are not trained to diagnose … so you get this cycle where you are getting people that are being referred to orthopedics inappropriately because it is not a surgical problem, but there should be some kind of in between non-operative orthopedic or even sports medicine that really focuses on the MSK problems and that is one part of this program that has worked ridiculously well"* Interventionist 1 - 6 month

Interventionists identified the need for an administrator to help facilitate the implementation of the program including coordinating participant schedules, reminders, and logistical day-to-day operations (e.g., room bookings, chart set-up, workflow).

Discussion

Summary of findings and recommendations for future trial

This pilot study evaluated the feasibility and implementation of the HLP, a novel 12-month complex behavioural lifestyle intervention comprised of participant-centred goal development, individualized action plan setting, and group psycho-education sessions. The findings showed that the protocol was feasible with minimal changes needed to conduct a larger, definitive trial. In terms of study protocol, the following are key recommendations to consider for a larger trial: active recruitment methods to target more male participants, use of a waitlist control group to improve retention rates, collecting baseline data prior to allocation and randomization to minimize missing data, and either simplify the costs and medical utilization log or leverage ICES (formally known as the Institute for Clinical Evaluative Sciences) data for an economic analysis.

In terms of program implementation, there are a few key changes to consider for a definitive trial. First, the program should continue to be delivered as a 12-month intervention as both participants and interventionists remarked that it afforded the time to make lasting behavioural changes. Second, some group psycho-social education programs can be delivered in an online format and the number of sessions should be reduced to reflect lower attendance observed by participants at the end of the program. Third, topics covered in the group-psychosocial program can be expanded to include for example more nutrition/cooking and the program should incorporate access to a gym or physical activity services. This would allow participants to implement their program learnings into practice.

Qualitatively, participants, interventionists and healthcare providers expressed acceptance of the intervention because it was holistic and aligned with the shared principles of

multidisciplinary care (e.g. collaboration, continuity of care, person-centred).[88] Quantitative data showed trends that the intervention improved mean goal attainment, depression and loneliness scores. However, this pilot study is not powered to detect changes and these results should be interpreted as suggestive findings.

Recruitment and representativeness

Recruitment was successful at reaching the 30-participant enrollment target within three months, exceeding about 50% of all randomized trials that do not reach their enrollment targets and subsequently extend their recruitment costs and time.[89,90] Comparatively, lifestyle or behavioural change trials report recruitment rates ranging between 30-78%.[36] The strategy of using passive recruitment methods[91] (i.e., local newsletter advertisements, word of mouth and posters) proved successful at generating interest in the study as 72 individuals initially contacted the program. As expected, the pragmatic design of a broad inclusion criteria resulted in a high eligibility rate of 97%. However, an exclusion criterion was added during recruitment for untreated and unstable health conditions to ensure participants were able to safely participate in group programing. In comparison to lifestyle trials with explanatory design, eligibility rates range between 16 to 66% and often exclude participants with multiple chronic diseases.[92,93] The advantage of incorporating broad eligibility criteria was to capture a representative sample of a population more likely to enroll in lifestyle programs in real-world settings, strengthening the study's external validity.

There was an overrepresentation of older adult females (81%) compared to the population of Hamilton, Ontario in the study sample. This is consistent with other lifestyle or behaviour change trials.[94,95] Lifestyle trials, specifically weight loss related interventions, tend to have an underrepresentation of males with the average study sample containing 27%.[94] Furthermore,

about a third of all lifestyle trials exclude males from their study, whereas about 5% of all lifestyle studies exclusively focus on males or male-specific health conditions.[94] Reasons for this gender bias are not well understood. One possible explanation is that males are less likely to exhibit health seeking behaviours towards medical and psychological interventions including participation in preventative services or health promotion activities.[94,96–99 100] As a result, it has been shown that males are more likely to delay routine check-ups, health consultations and underutilize clinically appropriate care.[96–98]

Another plausible but weakly supported explanation is that males exhibit greater self-efficacy towards self-directed behavioural change rather than through group setting interventions.[94] However, the rising prevalence of chronic diseases among male and female genders would suggest otherwise.[101] A review of randomized controlled trials for male inclusion showed that self-guided lifestyle interventions had a higher representation of males compared to counsellor or group guided lifestyle interventions, although this difference was not statistically significant.[94] Therefore, males may have greater interest in lifestyle interventions when delivered in a self-guided format. Nevertheless, there is an overwhelming lack of research regarding gender bias and the apparent lack of male inclusion to lifestyle or behavioural change trials.[99] This study highlights this concern for the risk of gender bias when scaling for a definitive trial. Therefore, potential mitigation strategies to increase the recruitment of males for a definitive trial may include using targeted recruitment methods (i.e., messaging), encouraging female participants to invite male participants (i.e., snowball recruitment of family and friends) and/or the delivery of online or self-paced group sessions to allow for some self-guided format.[102,103]

Education and income are key indicators of socioeconomic status.[104] Recruitment through passive strategies yielded a greater proportion of participants with an education attainment level

above high school compared to the sociodemographic composition of Hamilton, Ontario. The overrepresentation of highly educated participants was consistent with recruitment profiles of other lifestyle trials and it has been shown that passive recruitment strategies attract highly educated participants.[91,105] Considering that participants exhibited health seeking behaviour (i.e. motivated and ready to make behavioural change) to enroll in the study suggests that participants had some degree of health literacy, which is believed to be positively correlated with education.[106,107] Nevertheless, the recruitment process for a definitive trail may adopt a more targeted strategy to engage populations with lower formal education levels, especially considering that participants with lower education levels exhibit greater health risks and therefore, may have the greatest to gain from this intervention.[108]

Interestingly and somewhat contradictory, the proportion of participants with a household income less than $50,000 per year was higher compared to the population of Hamilton, Ontario, and for a study using passive recruitment strategies, given that education and income are highly correlated.[91] Unless lifestyle trials actively seek out and recruit participants from lower household incomes or from deprived areas this population is unlikely to be enrolled in studies. One explanation for our findings was our recruitment through Coffee News, a free newsletter found in the downtown core and other neighborhoods in Hamilton, Ontario, widely available in locations where low-income adults may frequent such as fast-food chains, local restaurants, and coffee shops. Conversely, we chose not to recruit through newspapers as they are often subscription based and would likely have excluded low-income populations. Another possible explanation is that this study's accessibility to public transit and no cost to enrollment may have been important implementation factors facilitating the enrollment of low-income individuals. Although access to care is a complex concept, geographic accessibility is considered an

important contextual factor that may act as a barrier or facilitator to enrollment.[109] In urban and semi-urban areas, poor transportation is commonly cited as a barrier to healthcare utilization resulting in unmet healthcare needs for segments of the population belonging to lower income levels. [110,111] Strategically implementing the HLP in a centrally located, accessible setting that accommodated mobility challenges likely facilitated the higher than anticipated enrollment of individuals with lower household income. Additionally, Hamilton, Ontario, has a low-cost transportation service for individuals with disabilities who are unable to access regular transit services .[112]

Although participants were not selected based on a chronic condition or poor health status, the majority of the study sample did self-identify as living with multiple chronic physical and mental health conditions and exhibited poor health outcomes at the beginning of the study. This overrepresentation of participants burdened by multimorbidity may be explained by the fact that individuals living with multimorbidity are more likely to enroll in lifestyle or behavioural change interventions as it is perceived as a holistic approach to care.[113] [114] It has been shown that individuals living with multimorbidity often perceive the lack of holistic care as a common barrier to engaging with the healthcare system that focuses on single disease management.[115,116] Multimorbidity is often associated with increased utilization of healthcare services, especially at the community level.[117–119] As a result, individuals burdened by multimorbidity may be more likely to seek health services or exhibit health seeking behaviours, however, these individuals are often excluded from randomized controlled trials.[120]

Further analysis of the study sample showed a recruitment profile that included an overrepresentation of participants exhibiting modifiable risk factors. There was a higher prevalence of obesity (65%) and lack of exercise (69%) compared to the Hamilton, Ontario,

population. This suggests that participants who were motivated to address weight loss may be more likely to seek lifestyle or behavioural trials. A similar recruitment profile (i.e., skewed towards those living with obesity) was observed in the HealthTrack study, a 2015 Australian lifestyle intervention .[121] However, the HealthTrack study excluded 51.5% recruited participants who were morbidly obese (>40kg/m2) due to the high likelihood of multimorbidities present but noted the high demand for lifestyle intervention at the community level.[121] Our findings confirm the demand for lifestyle intervention in Hamilton, Ontario, that is not well reflected in lifestyle or behavioural change trials with strict inclusion/ exclusion criteria.[122] Overall, the HLP was successful at reaching an at-risk population that would be likely to seek out a lifestyle or behavioural change program in the real-world community level setting.

The following are recommendations to further refine the recruitment and representativeness for a larger study:

A. Review and continue to use passive recruitment methods as in this pilot – posters, Coffee News advertisement, information at physician offices. However, the recruitment strategy can incorporate active recruitment methods and encourage participants to refer friends/families to target underrepresented groups, especially male participants
B. Consider developing online content to complement or substitute for group-psychosocial sessions to allow for self-guided learning as a means to improve recruitment and retention of underrepresented groups

Participation and retention rates

Participation (73%) and retention (53%) rates were lower than the 80% threshold considered adequate for randomized trials.[123] Achieving sufficient participation and retention

rates, especially for lifestyle trials that address mental health, is challenging for multiple reasons. There are psychological, physical and financial burdens associated with being part of any study, which may be more salient for lifestyle or behavioural change interventions that inherently require more time and effort, which is the opposite approach to the popular Westernized quick fix interventions.[124–127] Hence, most published trials range from 6-12 weeks, instead of 12 months such as in this pilot.[127] Notably, the Medifast program reported a retention rate of 26% after 24 weeks,[128] the Jenny Craig program with 60,000 participants had a retention rate of 6.6% after 52-weeks,[129] diabetes prevention programs report retention rates of 10.4% after 52-weeks[130], and other high intensity lifestyle intervention programs report a retention rate of 37% after 52-weeks. [130] A Cochrane review of 19 studies assessed the effects of goal setting and action planning for adults with chronic health conditions, however, only one study had enrolled participants with multiple chronic conditions.[93] Their one-year retention rates were 61% for intervention group and 57% for control,[131] which was comparable to the HLP (60% intervention group and 47% comparator group). Given these considerations, the HLP's 12-month retention rates were relatively high and may be partly explained by the financial incentives and pre-notifications provided to participants, which are proven methods with positive effects on retention in other mental health trials.[127] However, research is beginning to identify motivation and readiness for change as key psychological factors facilitating the recruitment, attendance and adherence to lifestyle trials.[132]

Interestingly, the differences in retention rates between intervention and comparator groups may suggest that high intensity lifestyle interventions have greater acceptability and are well suited to retaining participants with chronic mental and physical health issues. There is some evidence to support this finding. In a systematic review of 28 pragmatic lifestyle

interventions from the United States, qualitative data showed that retention rates were related to participant perceptions of how likely the intervention was to be effective by its intensiveness rather than duration.[133] Similarly, a review of four large lifestyle interventions observed that the intensity of interventions were positively correlated with intervention efficacy.[134] Therefore, the lower retention rate observed among the comparator group could be explained by having enrolled motivated individuals who were ready to participate and make a change, but subsequently disappointed when allocated to the comparator group, as they perceived it as less salient of an intervention.[124] This may explain the loss to follow-up at the start of the study among comparator group participants who did not provide a reason for non-participation (n=3). Furthermore, comparator group participants felt that the 3-month interaction with the program was inadequate, in terms of frequency, to successfully maintain their goals.

The pilot study used a comparator group that had participants set individualized goals and action plans with the aid of a research assistant. Although the comparator group was justified as the aim of the pilot study was to compare the intervention to what is expected in real-world clinical settings as recommended by clinical practice guidelines[135–137], it may not be feasible or helpful to continue with a comparator group for the larger trial. Furthermore, conducting a comparator or even a traditional placebo control group for an entire year is not expected to provide any further useful data, would require a considerable amount of resources and will likely underestimate the effect of the intervention.[138] This is because it is difficult to blind the subjects to control or active comparator group, likely causing participants to drop out or seek additional treatment outside of the study, and it is difficult to identify a control that is inactive but equally credible to participants.[139] For these reasons, a waitlist control group receiving usual care, might be more appropriate for a larger trial. The waitlist control group would follow usual care by their

primary care providers during the first year enrolled in the study. They would then be given the intervention. Having a waitlist control group that will receive the intervention is expected to increase the 12-month retention of participants in the comparator group .[140] Although there is a risk of loss to follow-up with a12-month waitlist, providing a financial incentive for data collection, describing the 12-month waitlist as a necessary baseline, and knowledge of receiving the intervention may be sufficient to retain participants.[141] For instance, at the end of the HLP study, participants in the comparator group casually express interest to enrol in the intervention program. Usual care compared to the intervention trial will also allow for better cost-effectiveness measures, which would provide more relevant information during analysis.

The following are recommendations to improve participation and retention rates for a definitive trial:

A. Consider wait list control trial design to improve retention rates in the comparator/control group;
B. Consider the addition of an exclusion criterion for untreated and unstable health conditions, defined as having symptoms from established health conditions that interfere with activities, such as travel and keeping appointments, at least twice a month or more, as this was one of the main reasons for recruitment and attrition issues in the pilot.
C. Continue financial incentives and reminders to participants for data collection;
D. To ensure adequate power of a larger trial, increase the sample size to account for the loss to follow-up observed in this pilot.

Missing data and data collection

There was minimal missing data (<1%) for participant-centred outcomes across the 12-months with five follow-up assessment periods. This indicates that the trial was feasible from a data collection perspective, but it was a resource intensive and time-consuming process. Although multiple follow-up periods increased the power of the GEE analysis with no observed harms, it may be logistically beneficial to reduce the number of follow-up assessment periods. The high data completion rate may be attributed to the use of the REDcap system that made it practical and easy to record outcomes and identify incomplete data in a timely manner. This process of data quality assurance allowed for accurate and robust data collection and should be implemented in the larger trial. Additionally, providing financial incentives during assessments may have alleviated any financial burdens associated with participating in the study, for example cost associated with parking.[142] However, there were a few implementation challenges during the assessment process. This included GAD-7 (anxiety) scales inconsistently administered due to technical settings in REDcap and lack of appropriately large blood pressure cuffs at baseline. These issues were quickly identified at the beginning of the study and subsequently resolved. Furthermore, data collection did vary for the costs and medical utilization log because often participants neglected to track their medical utilization over the 3-month intervals. For a definitive trial, it may be more feasible, reliable and valid to obtain this information through Ontario Health Insurance Plan (OHIP) administrative data from IC/ES. However, the limitation is that OHIP administrative data would not capture out-of-pocket expenses and non-OHIP covered services. Finally, baseline data was inconsistently collected for participants who withdrew early from the study because it was collected after randomization and allocation to streamline the participant enrollment process. A future study protocol may consider collecting

baseline data prior to allocation and randomization to ensure completeness of data and using intention to treat analysis.

Several overlapping scales were used to determine best fit for a definitive trial. The intervention did appear to have a potential effect on general health quality of life measure for the RAND-SF36 but not the HUI scale. This is likely because the RAND SF-36 general health measure is a composite of 5 questions, whereas the HUI general health measure is a single item question. Therefore, it is plausible that the RAND SF-36 general health measure was more sensitive to change compared to the HUI general health measure. Although we did observe non-statistical improvements to quality-of-life measures for both RAND-SF36 and HUI, the interpretation of these findings is limited without an adequately powered sample. In terms of implementation of the two quality of life scales, it may be less resource intensive to analyze one scale for a definitive trial, in which case the RAND-SF36 would be easier to analyze and report. However, the findings from this study cannot suggest if one tool is superior to the other for a cost-effective analysis in a larger trial. Likewise, the 10-item PSS was observed to be more sensitive to change than the 4-item scale.

There were no observed changes to anthropometric outcomes, except for a small change in waist to hip ratio. There are several plausible explanations as to why the intervention did not show an effect on anthropometric outcomes. First, lifestyle interventions alone have shown varied effects on weight management, rather lifestyle interventions with an exercise and diet component are more likely to be effective.[143] Access to exercise facilities was not part of the intervention. Second, there were measurement errors and inconsistencies with regards to anthropometric outcomes during the study for blood pressure measurements, waist, hip and height measurements. Third, it could have been possible that participants were losing weight but

gaining muscle mass during the study. Fourth, because participant-directed goals are individualized and co-developed with the healthcare team, the focus of the intervention was on healthy lifestyle changes and addressing more salient risk behaviours and health outcomes like anxiety, pain management, depression, etc., to increase uptake and acceptability of the program rather than weight loss.

The following are recommendations to improve data collection procedures:

A. Consider collecting baseline data on all participants at the time of informed consent and before randomization.
B. Review and continue using current data collection methods including quality assurance procedures. However, as no harms were found, consider decreasing amount of data collection times to every 6-months;
C. Either simplify the costs and medical utilization form to reduce missing data or collect participant's medical utilization data from ICES;

Attendance

Attendance at individualized program components were 100% for both groups. For the intervention group (n=9), the group psycho-educational sessions were reasonably well attended on a weekly basis, with a mean decline in attendance over time.

The following are recommendations for attendance:

A. Reduce the frequency of group psycho-educational sessions from weekly to bi-weekly over the latter part of the 12-months to coincide with the observed decline in attendance.
B. Consider including online programming to facilitate attendance

Other implementation and intervention considerations

Program components

The process of capturing patient-relevant goal attainment and providing feedback to participants to practice behaviour change during the individual and group sessions were valued by both participants and interventionists. Evidence suggests that goal setting and action planning is more effective when paired with consistent monitoring and feedback, if the goal is difficult, and if peer support is available. [144] Additionally, greater intensity of the intervention (i.e., engagement) is an important factor associated with improving mental health outcomes like depression.[145] Group sessions have been shown as effective ways to improve loneliness,[146] which is further supported by the positive correlation between attendance and mental health outcomes, specifically loneliness scores, in this study. Considerations for a future intervention included to expand group session topics around nutrition, to incorporate family programming and community supports, and to include physical activity or exercise components to allow participants to apply their knowledge to practice.

Duration of program

Participants, interventionists, and healthcare providers emphasized the importance of delivering the intervention for a minimum of 12-months. Although studies show that lifestyle interventions delivered within a short period of time can produce promising effects, often these effects do not last over long periods of time.[147,148] This is because behavioural change is complex, difficult, takes time to achieve, and rarely occurs in a straightforward, linear way.[149,150] Rather, relapses are common when achieving one's goals.[151] Therefore, having the intervention delivered for 12-months likely empowered participants to build the necessary skills to prevent relapses from affecting their goal attainment and mental health outcomes. Although a 12-month program requires a great deal of resources, this study showed preliminary improvements in

outcomes like goal-attainment, depression, loneliness and general health after 12-months. These findings align with multiple guidelines including the American Heart Association, American College of Cardiology, and The Obesity Society who have suggested there is strong evidence to recommend the use of high intensity lifestyle interventions for 6 or more months to realize health benefits.[130,152,153] Furthermore, authors from the RADIEL study (2017), which examined cardiometabolic health among women after 6 years post intervention, attributed the absence of long-term effects to the high prevalence of gestational diabetes mellitus requiring participants to seek additional lifestyle advice and intensive follow-up with the healthcare system masking the effect of the intervention. [147] This suggests that short-term lifestyle interventions do not sufficiently meet the needs of higher risk populations that the HLP enrolled.

Location of program

Participants and interventionists liked the central and accessible location of the programs, including closeness to bus routes, elevators, and accessible restrooms. If physical activity or exercise components are added to the program, a location with all these amenities would be needed.

Program resources

Participants perceived the specialized intervention healthcare team as a valued and important program resource. The intervention healthcare team with significant skills and training in primary care, CBT, nutrition, and musculoskeletal system were able to diagnose and provide treatment needed to address the complexity of health issues and concerns of participants. Although the comparator group, delivered by an interventionist trained in theories of health behaviour, was able to facilitate the development of participant goals, greater change in outcomes and participant satisfaction was noticed among intervention participants. The

preliminary effectiveness of the program can be attributed to the knowledge and skills of the healthcare team in addressing healthy lifestyle changes, which may be a barrier in the primary healthcare system. [154] Other barriers to the successful implementation and sustainability of behavioural change interventions is finding the time, confidence and resources for primary care physicians to deliver and integrate these interventions into their clinical practice. [155]

A larger study would require significantly greater time and resources to schedule and prepare charts and program documents, therefore logistical and administrative support would be needed to ensure efficient workflow.[156,157] The intervention is relatively intensive presenting significant costs to deliver, and although an assessment of cost and benefit was not conducted in this pilot, these costs may be offset by lower utilization of other healthcare services and increased productivity from improved health outcomes.[154] Additionally, providing group-based psycho-educational sessions is one method of keeping the overall costs low. [152] There may be some flexibility in the delivery of the group psycho-education sessions. Whether this includes a combination of in-person and online delivery or strictly online would require further considerations. Due to the COVID-19 pandemic and social distancing requirements, offering this program virtually might provide an opportunity to reach those who are most in need. Nevertheless, given the need to reschedule some sessions due to bad weather, having online or virtual group-psychosocial sessions may improve accessibility of sessions for participants. Finally, interventionists and research assistants volunteered their time to deliver the HLP, however, this may not be a realistic expectation and therefore, there are additional costs to consider for the development of a larger trial.

Strengths and Limitations

A strength of this study was its pragmatic trial design and robust quantitative and qualitative evaluation using the REAIM framework. The advantage of using this approach was that it combined research elements with real-world practice. For instance, the minimal inclusion and exclusion criteria allowed for the enrollment of a heterogeneous study population increasing the generalizability (external validity) of the trial results. Additionally, using the quantitative and qualitative evaluation approach allowed for the exploration of contextual factors, process and outcomes measures to better understand the programs' feasibility and implementation. It has been shown that many clinical trials often lack the necessary information to operationalize the intervention for real-world healthcare settings.[158] As a result, it can take more than a decade to translate research into clinical practice.[158–160] Additionally, the evaluation used data from multiple stakeholders providing greater context and perspectives regarding the results. The robustness of the results from this pilot study will help to inform a larger trial by better understanding elements of the intervention that were successful and elements that require changes for future implementation.

Limitations are related to the pilot nature of the study, which include the small sample size, a single centre study, inability to blind participants, and using a comparator group that dilutes the overall effectiveness of the results. However, the comparator protocol does mimic an intervention that one could expect to receive in a real-world setting, although seldom does, which allows for greater applicability and generalizability of findings to inform implementation research. In the analysis, confounders such as age and gender were controlled, however, due to the small sample size and unequal balance in gender distribution this may have introduced some spurious results. The effectiveness analysis does not control for multiplicity because the goal was to explore relationships within the data and potential impact on outcomes. Therefore, regardless

of statistical significance, findings are interpreted as preliminary. All the mental health outcome measures were self-reported; however, social desirability and selective recall bias were minimized by having research assistants collect data and by using online self-administered survey tools. The blood pressure and height measurements had a great deal of variation that may limit their accuracy and precision, this is most likely due to measurement error due to having multiple individuals collecting data and equipment limitations. GAD-7 scores were incomplete due to inconsistencies in the data capturing process at the beginning of the trial.

Implications for practice

The long-term goal of this study is to improve health outcomes by empowering individuals to make healthy lifestyle and behavioural changes. This study has highlighted the interest, need, and acceptance of lifestyle or behavioural change interventions among participants with chronic diseases in Hamilton, Canada. The HLP is a novel method of translating applied evidence-based practice to a real-world community setting. This included co-developing person-centred health-related goals and action plans, and addressing mental health and behavioural health topics through group-based psychoeducation sessions..[161] The pilot study of the HLP showed evidence that the program aligned with the quadruple aim of healthcare systems as it was valued by participants and providers and has the potential for improving health outcomes. In terms of cost, a definitive trial would be needed to understand the potential cost-savings to the larger healthcare system.

Conclusion

The HLP is a novel 12-month complex intervention to address behavioural or lifestyle risk factors for a population that is burdened by multimorbidities. This pilot study showed that the HLP study protocol is feasible and acceptable to implement within a community-based

setting. Although the study lacked power and assumptions should not be made regarding the intervention effectiveness, it was observed that the intervention improved mean goal attainment scores, depression, and loneliness for participants. We recommend that there is sufficient evidence presented in this paper to justify moving forward with a large scale, definitive trial with minimal changes recommended for the study and the intervention.

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Appendix A: CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial [162]

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	iii
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	iii – iv
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	1-3
	2b	Specific objectives or research questions for pilot trial	3 - 4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	7-8
Participants	4a	Eligibility criteria for participants	7 -8
	4b	Settings and locations where the data were collected	7
	4c	How participants were identified and consented	8 -9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10 -11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-20
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
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	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9

Blinding	11 a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9-10
	11 b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	20-22
Results			
Participant flow (a diagram is strongly recommended)	13 a	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	23
	13 b	For each group, losses and exclusions after randomisation, together with reasons	24
Recruitment	14 a	Dates defining the periods of recruitment and follow-up	24
	14 b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	26-27, 28-29,
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	24
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	28-31
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	25
	19 a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	57
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	56-57
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	42-59
	22 a	Implications for progression from pilot to future definitive trial, including any proposed amendments	42-59
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	22
Protocol	24	Where the pilot trial protocol can be accessed, if available	22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA
	26	Ethical approval or approval by research review committee, confirmed with reference number	22

Appendix B: Delivered programming of group psycho-education and wellness sessions.

Session	Programming Topic
1	Introduction to program
2	Identifying health goals
3	Healthy mindsets and stress management
4	Creating a life compass
5	Building resources
6	Active lifestyles
7	Healthy nutrition
8	Identifying and overcoming challenges
9	Finding motivation
10	Problem-solving barriers
11	Problem-solving barriers
12	Problem-solving barriers
13	Brainstorming group session
14	Brainstorming group session
15	Brainstorming group session
16	Increasing self-efficacy
17	Problem-solving barriers
18	Brainstorming group session
19	Mindful eating & small group work
20	Problem-solving barriers
21	Problem-solving barriers
22	Problem-solving barriers
23	Problem-solving barriers
24	Willpower & ties to vision, mission, and values
25	Self-regulation
26	Resilience
27	Planning for winter
28	Willpower
29	Chronic pain
30	Open discussion
31	Open discussion
32	Intentions
33	Mindfulness
34	Back to basics

35	Barriers
36	The self within us
37	Review
38	Review
39	Review
40	Review
41	Review
42	Review
43	Graduation Ceremony

Appendix C. Timeline of program and evaluation (data collection) components.

Timeline	Intervention + Usual care	Comparator + Usual care
Randomization		
Baseline	A C D	B D
3- Month	A C D	B D
6-Month	A C D E G	B D E G
9- Month	A C D H I	B D H I
12-Month	A C D E F G	B D E F G

A	Monthly visits with healthcare team (Primary care physician with CBT training, Dietician, and MSK specialist) to develop goals and action plans. Community support linkages provided.
B	3-month visit with a research assistant to develop goals and action plans. Community support linkages provided.
C	Weekly group psychosocial educational sessions; attendance optional.
D	3-month collection of health outcomes, and cost and medical utilization log.
E	Semi-structured interviews with interventionists (N=4).
F	Semi-structured interview with participants from the intervention group (N=9) and comparator group (N=7).
G	Semi-structured interview with participant's healthcare providers (N=3).
H	Focus Group with participant family members (comparator group N=2, intervention group N=1).
I	Participant feedback survey from intervention group (N=9) and comparator group (N=7).

= program components = Data collection/ evaluation components

Appendix D: Qualitative Data Collection Tools

1. Participant semi-structured exit interview guide (30-60 minutes), 12months

Participant ID_____ Date_____
Location_____ Researcher_____
Start time_____ End time_____ Date of informed consent _____
OK to record: Y / N

Thank you for agreeing to be part of this study. Do you have any questions before we start?

1) What do you think of the program overall? Prompts: helpful/not helpful, too busy/not enough contact

2) Have you been able to make any sustainable lifestyle changes? If so, do you feel the program has contributed to you achieving this/these? If no, what has stood in your way of making these changes?

3) What is the most important/interesting thing you have learned through the program?

4) What has/have been the most useful component(s)/part(s) of the program? Prompt: meeting with the physician, dietician or physical therapist, education sessions, support group meetings, identifying health goals, developing an action plan...

5) What are some other useful aspects of the program? Prompt: admin support, reminders

6) What was not useful? Could this aspect of the program be changed to make it more useful? If yes, how? Should this part of the program be taken out? If so, why?

7) What is not currently part of the program that would be useful to include, if possible?

8) Is the length of the program appropriate for meeting your/the program's objectives? Should the program be shorter, longer or stay the same (1 year). Why? Are there components of the program that should be extended? Prompt: support groups, education sessions, check-ins every few months?

9) What do you think the role of the family is with regards to leading a healthy lifestyle? Prompts: verbal support, joining in, community-building, none.

10) What do you think the role of the community is with regards to leading a healthy lifestyle? Prompts: providing safe places to exercise, healthy public policies, community support groups, activities, none

11) Have you/Has the program been able to make an impact on anyone else whom you know? If yes, how so? Prompts: Family, friends, co-workers, policymakers

12) Is there anything that has not been covered, which you would like addressed?

Thank you again for your time.

2. Staff semi-structured interview guide (30-60 minutes), 6 and 12 months

Participant ID_____ Date_____
Location_____ Researcher_____
Start time_____ End time_____ Date of informed consent _____
OK to record: Y / N

Thank you for agreeing to be part of this study. Do you have any questions before we start?

1) What is your role in the Healthy Lifestyles Program? How long have you been working in the Program? Has your role changed throughout your time in the Program? If so, how?

2) What aspects of the Program are you involved in? Prompts: education sessions as developer or support

3) What aspects of the Program work well? Prompts: components of the program, time spent at work, administrative support

4) What aspects of the Program do not work well? Could these aspects be improved? If so, how?

5) What is not currently part of the Healthy Lifestyles Program that would be useful to include, if possible?

6) What supports/resources would you need to improve your work within the Program?

7) Do you feel aligned with the vision, mission and values of the Healthy Lifestyles Program? If so, how? If not, what would need to change to make these more relevant to you?

Only for the 12 month interview - 8) Is the length of the program appropriate for meeting your/the Program's objectives? Should the program be shorter, longer or stay the same (1 year). Why? Are there components of the Program that should be extended? Prompt: support groups, education sessions, check-ins every few months?

8/9) Is there anything that has not been covered, which you would like addressed?

Thank you again for your time.

3. Healthcare providers semi-structure interview guide (15-45 minutes), 6 and 12 months

Participant ID_____ Date_____
Location_____ Researcher_____
Start time_____ End time_____ Date of informed consent _____
OK to record: Y / N

Thank you for agreeing to be part of this study. Do you have any questions before we start?

1) What is your role as a healthcare provider?
Prompts: Family physician, dietician

2) How did you hear about the healthy lifestyles program? How have you been involved with the healthy lifestyles program? What aspects of the program are you involved in? Prompts: have patients/family members in the program

3) What is your understanding of the healthy lifestyles program? MIP and/or LIP
Prompts: What does the program do or what is its purpose?

4) What is your current perception of the program?
Prompts: it works well for my patient, it has not made a difference, my patient is disappointed

5) How has your perception of the program changed over time?

6) Have you communicated with the staff of the program? If so, in what capacities?

7) From your understanding, what aspects of the program seem to work well?

8) From your understanding, what aspects of the program do not work well? Could these aspects be improved? If so, do you have any suggestions?

9) What is not currently part of the program that would be useful to include, if possible?

10) What supports/resources could the program help you with, if any, for your practice?

Only for the 12 month interview - 11) Is the length of the program appropriate for meeting your patient's objectives? Should the program be shorter, longer or stay the same (1 year). Why? Are there components of the program that should be extended? Prompt: support groups, education sessions, check-ins every few months?

11/12) Is there anything that has not been covered, which you would like addressed?

Thank you again for your time.

4. Families focus group guide, 9 months

Date and time _____ Location _____
Researcher(s) and role(s)_____
Attendees(s)_____
_____
_____
_____
_____

Make sure to have room set-up, have recorder(s) and other supplies (e.g., snacks, consent forms), make nametags – for people and on table.

Thank you for taking the time to meet for this focus group. My name is _____ (present rest of research team in attendance). I will go over some information first and then we will get started. The purpose of this session is to gather evidence to help improve the healthy lifestyles program and the way the program is provided and to understand the roles of families on changing health behaviours. Any information gathered here will not be attributed to any individual speaker. In other words, your name will not be presented with specific comments. However, there is a chance that you or others could be recognized by the things you say. Every attempt will be made to keep the information anonymous. Also, these sessions follow the values of the healthy lifestyles program: Supportive, evidence-based, responsive, respectful, positive. Please attempt to have everyone contribute in a respectful manner and keep the information presented here confidential. In other words, please do not share this information with people not in this session. If you think of something relevant after the session, you can send it to me or we can meet afterwards. I will be recording the session with a digital recorder, and I, as well as other research members, will be taking notes. Please make sure you have a signed consent form. [Go over forms, ask if there are any questions, and gather forms if do not have already.]

1) Please go around and introduce yourselves and describe your role with regards to the person in the Healthy Lifestyles Program. Prompt: husband, wife, partner, child

2) How did you hear about the healthy lifestyles program?

3) How did you react when your family member told you s/he was going to be part of this program? Why?
Prompts: Supportive/not supportive

4) Have you noticed any changes in your family member?
Prompts: happier, more/less focused, around less, more stressed

5) What do you think the role of the family/friends is with regards to leading a healthy lifestyle? Prompts: verbal support, joining in, community-building, none

6) What challenges do you see in leading a healthy lifestyle from the perspective of being a family member? In other words, what makes it difficult to support others in leading a healthy lifestyle? Prompts: do not want to change own routines focused on health, not supportive, don't feel the other person needs to change,

7) Do you see any ways to overcome these challenges?

9) Is there anything that has not been covered, which you would like addressed?

Thank you again for your time.