

Alvarez, Study proposal, Feasibility and implementation of a healthy lifestyles program: A pilot study

Official title of the study: Feasibility and Implementation of a Healthy Lifestyles Program: A Pilot Study

NCT Number: 03258138

Date of document: December 11, 2017

SIGNIFICANCE AND IMPACT OF THE RESEARCH

Background and rationale of study

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

There are some simple, yet effective, lifestyle (e.g., behavioural) interventions which have been shown to improve the signs and symptoms of many chronic conditions. These interventions include eating a healthy diet, having proper and sufficient sleep, managing stress, smoking cessation, improving socialization, and being active, among others. (9,10) Cognitive behavioural therapy (CBT), in particular, has been shown to help with weight loss, to improve insomnia, and to decrease symptoms of anxiety and depression. (11–14) Mental health can play a role in the ability to seek out and follow through on the changes necessary to achieve or maintain a healthy lifestyle, yet this aspect is rarely addressed in chronic disease self-management or weight-loss programs. Access to mental health services is limited in Ontario by a lack of providers and non-coverage of services by the Ontario Health Insurance Plan (OHIP). (15–17) Therefore, many individuals go undiagnosed or untreated.

Furthermore, individuals are shaped by the society in which they live. Determinants of health, such as income security, the built environment, and air quality, among others, play a role in weight management and in the development and progression of chronic conditions. The determinants of health can also act as barriers to achieving healthy lifestyles (e.g., lack of socialization, unsafe neighborhoods). There is simply not enough time in a regular office visit to address a whole range of possible individual barriers. Even with the time, most physicians do not have the training to deal with these issues or have an in-depth knowledge of community services available to patients and their families.

Person-centered care

While many studies continue to look at the effects of lifestyle modification on chronic conditions, aging and longevity, it is just as important to develop programs that encourage individuals to adopt healthier lifestyles and for communities to support individuals in leading these healthy lifestyles. (10,11) Changing habits takes time and requires the use of multiple techniques based on patient needs. This type of person-centered care is a different approach than simply bringing more services to one location, or having services follow individuals. (18–20) This approach starts by attending to the needs of the individual (e.g., improving mood, finding motivation, learning strategies to combat social isolation) instead of the pre-set indicators typically used to determine success in the clinical care of chronic conditions (e.g., lipid levels, asthma control, smoking cessation). The hypothesis is that approaching problems from the individual's perspective (i.e., working on what is important to the patient) and providing the tools, skills and supports to meet self-identified goals, will lead to more sustainable improvements in health-related quality of life and healthier habits, which in turn lead to improvements in the clinically-relevant indicators. These approaches are not new and have been used in the setting of addictions and health promotion. (21,22) However, using these techniques is not mainstream in the clinical setting and few individuals have access to behavioural therapists. A new, multidisciplinary, person-centred, holistic and evidence- and practice-based healthy lifestyles program has been created to address these needs. This proposal aims to evaluate the feasibility and implementation of the healthy lifestyles program through a pilot

study. It will also be important to evaluate this program to determine if, and what components of, the program are effective. These answers will be needed so that the program may be improved and scaled-up to other sites.

Novel intervention

Each individual will be enrolled in the healthy lifestyles program for one year. This amount of time allows for determination of participant goals, identification of barriers and facilitators, healthy lifestyle education, and trial and modification of individualized action plans. To achieve these goals, participants will meet weekly for group health and wellness learning sessions or brainstorming group sessions. The health and wellness learning sessions provide a platform for concepts from a variety of health behaviour theories and CBT to be combined with evidence- and practice-based recommendations for healthy lifestyles. (11,23–29) These provide the basis for the individualized action plan. Monthly individual sessions with a family physician trained in medical CBT, a dietician and a physical therapist help individuals tailor their action plans and recommendations to their particular circumstances and provide supports based on their needs. (30,31) The brainstorming group sessions allow for facilitated discussions where individuals explore barriers and facilitators to achieving their goals and provide an interpersonal component to the program through the building of social interactions. Participants will also receive help in finding community programs to support healthy lifestyles.

An ecological approach to behavior change is used throughout the entire program. An ecological perspective allows for the inclusion and assessment of factors at the individual, interpersonal, institutional or organizational, community and policy levels. (24) In addition, Prochaska's stages of change, or transtheoretical model, is used to identify in which stage each participant is in for each health goal. These stages include precontemplation, contemplation, preparation, action, maintenance and relapse. (32–34)

Preliminary evidence to support this approach

Modified versions of this program have been used in presentations to graduate students on stress management (35) and time management (36) and in a classroom setting through a Theories of Health Behaviour course taught by the principal investigator in three different sessions (Spring/Summer 2016, Fall 2016 and Spring/Summer 2017) at McMaster University. In addition, a pre-trial test run recently completed with 9 individuals enhanced the style of delivery, format and content of the 8 core initial health and wellness learning sessions and the initial assessment segments of the program. While these results are not published, feedback from students and from participants in the pre-trial test have been positive for the content and structure as well as for reinforcing the ability of the program to address gaps in current care.

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

Table 1 provides a more detailed listing of components for the program and its related research activities. All tables in this document follow the format used by Samaan et al (37). The intervention group participants will receive the full healthy lifestyles program with the weekly group sessions and with individualized monthly meetings with team members. They will develop individualized health goals and an action plan as well as receive supports for identifying barriers and facilitators to changing behaviours and for community supports. They will continue to receive usual care from their current healthcare providers (see below).

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

Currently, family physicians do give advice on healthy lifestyles. In addition, many Family Health Teams (FHTs) in the Hamilton area have complementary professionals, such as dietitians and social workers. However, care has still traditionally focused on meeting healthcare-set or guideline-directed care and, at times, the multi-disciplinary approach has not translated into integrated care. It is difficult to address the “how-to” in clinical settings. Time limits do not allow for a holistic approach to barriers or for teaching problem-solving skills, and payment schemes have drawn attention to physically based and acute treatment of conditions. It is not standard to have patients develop health goals that receive as much merit as medically directed goals. Therefore, individuals in the control group will develop health goals with the support of a research assistant trained in theories of health behaviour, and progress on these goals will be measured. However, the “how to” put these goals into practice will not be provided as the means to test the healthy lifestyles program. The hypothesis is that developing health goals may help individuals attend to improving their lifestyles, but having the “how to” will provide more movement in the stages of change necessary to carry out the proposed actions and will lead to improved outcomes. Because there is still an intervention, but it is modified, the control arm participants will be receiving a less intensive program (LIP). The LIP arm will also be referred to as ‘the program’ for the purposes of documents used in the study. This is done so that participants in both arms can relate to the questions asked and the forms can be standardized as much as possible. It will be important to note if simply developing health goals and having a modified treatment is sufficient to change habits.

Usual care

Both arms will continue to receive usual care as provided by their healthcare practitioners. The programs are meant to be adjuncts to usual care and deal with the prevention and management of chronic conditions from cognitive and behavioural perspectives where lifestyle changes are more likely to influence outcomes. No drug treatments or changes will be made through the study. If there are any significant changes to an individual’s health status, these will be communicated to the family physician, provided consent has been given by the participant. Furthermore, the number of visits to health providers will be captured through a costs and medical utilization log in both groups. This will help provide a truer representation of the time and costs involved in taking part in the programs. Lastly, in order to get a sense of clinicians’ perspectives on both programs, the study will include interviews with participants’ healthcare providers to obtain their views on these programs and/or development of patient goals and their perspectives on the influence of these programs on their patients’ wellbeing.

Table 1. Components for healthy lifestyles program pilot study

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

Legend: S – Session (1hr); S1 – Introduction to Program; S2 – Identifying health goals; S3 – Healthy mindsets and stress management; S4 – Creating a life compass; S5 – Building resources; S6 – Active lifestyles; S7 – Healthy nutrition; S8 – Identifying and overcoming barriers; S9 – Finding motivation; S10 – Living your values and addressing life changes and adversities; S11 – Advanced stress management techniques; S12 – The self within us; S13 – Building healthy relationships; S14 – Advanced time management techniques; S15 – Increasing self-efficacy; S16 – Increasing your social circle; S17 – Mental wellbeing and chronic pain; S18 – Revisiting goals and reflecting on self-growth; BG – Brainstorming group session (1hr); PAJ – Physical activity journal; NJ – Nutrition journal; Scs – Scales, including The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+), quality of life scales (SF-36 and HUI2/3), Patient Health Questionnaire (PHQ), Insomnia Severity Index (ISI), Perceived Stress Scale, Life Change Index Scale, and DeJong Gierveld 6-item Loneliness Scale, PSSI – Participant satisfaction survey intervention arm, PSSC – Participant satisfaction survey control arm; C&MU – Costs and medical utilization log; IA – Individual initial assessment (3hrs); F/U – Individual follow-up visit (1hr); DC/L&M – Data collection form with labs (HbA1C, fasting lipids, and CBC as dictated by current guidelines) and measurements (blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Scale (if relevant); EI – Exit interview; SI – Program staff interviews; FFG – Family focus groups; HCI – Healthcare provider interviews; Ceremony – provided for participants and family/friends along with certificate of completion of the Program.

Research questions and study hypothesis

This proposal lays out the plans for a pragmatic mixed methods study. This study design allows for the flexibility and responsiveness needed to study multiple dimensions of a new program, especially one designed for creating healthy lifestyles through the development of participant-directed goals and individualized action plans. (38–41). The proposal lays out the plans for a pilot phase.

Primary research question and main study hypothesis:

Does a holistic program based on CBT and behavioural theories provided through group and individual sessions over a year compared to usual care along with development of health goals help meet participant-directed and clinical outcomes for adults in the Hamilton area?

We hypothesize that the MIP will be feasible and acceptable and will be more effective for helping participants move across stages of change and for meeting goals than the LIP.

Sub-questions for this pilot study:

Quantitative research questions

- 1) Are participants meeting their self-identified health goals?
- 2) Are there impacts seen on other health indicators?
- 3) Are there specific participant characteristics (e.g., gender, age) that correlate with these outcomes (i.e., meeting self-identified goals, other health indicators)?
- 4) What are the costs of running the programs, and how do these compare to costs of usual care?

Qualitative research questions:

- 1) How do the interventions affect the participants, and do the interventions meet participant expectations and needs?
- 2) How does the MIP affect the staff providing this intervention, and what do staff suggest can be done to improve the program or its provision?
- 3) How does the MIP affect the participants' families, and what is the role of families in adopting healthy lifestyle changes?
- 4) How do other providers involved in the participants' care view the program(s) and their patient's involvement in the program(s)?
- 5) What is the context within which the programs are being implemented?

Mixed methods questions:

- 1) Are the programs meeting their objectives?
 - a. Process indicators – both quantitative data (e.g., number of participants recruited, number of participants developing health goals, participant satisfaction with the program as data collected through surveys) and qualitative data (e.g., participant satisfaction with the program as data collected through interviews)
 - b. Short-term indicators – both quantitative data (e.g., number of participants finishing the programs) and qualitative data (e.g., information gathered through in-depth semi-structured exit interviews)
- 2) Are the programs feasible?

Overall goals and objectives

The goal of this pilot project is to determine the feasibility and implementation of the full healthy lifestyles program (MIP) in a real-life setting in the Hamilton area. Multiple aspects of the MIP will be studied to test the concept of the program, improve the program, examine the context and implementation of the program, and determine its effectiveness, cost-effectiveness, and feasibility. This pilot study will also identify the conditions for a larger randomized controlled trial to further evaluate effectiveness and cost-effectiveness, especially when the program is run at full capacity. Evaluating the context of this pilot phase will also help determine if, and how, the program should be considered for scaling up in other parts of Canada and/or internationally, and whether this is a cost-effective and sustainable adjunct to address the needs of patients and service providers in dealing with chronic conditions. The control group will help determine if the LIP is just as useful, keeping in mind these are small numbers, so findings cannot be generalized from this study.

Primary objective:

To study the feasibility and implementation of the MIP

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

Secondary objectives:

To determine changes in participant-directed and clinical outcomes

- 1) To determine changes in participant-directed outcomes through goal development and associated measures
- 2) To determine changes in clinically relevant outcomes, such as health-related quality of life, anxious and depressive symptoms, sleep, loneliness, stress, other health indicators (HbA1C, fasting lipids, and complete blood count (CBC) as dictated by current guidelines) and measurements (blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, Edmonton Obesity Scale (if relevant))

Anticipated project contributions

This pilot phase is to assess the feasibility and implementation of the full healthy lifestyles program. However, in the longer-term, findings of this and future research in this area are expected to address gaps in knowledge around individuals' attainment of healthier lifestyles and around which services can be provided to support these changes. In addition, the findings will inform future research, practice and policies around healthy lifestyles. The impact on participant experiences and outcomes is one of the main objectives of this study. The healthy lifestyles program is person-centered in that it allows for participants to self-identify relevant health goals and to develop realistic and sustainable action plans to achieve their goals. The

purpose of evaluating the healthy lifestyles program is to understand if and how it works, to iteratively improve the program, and to understand the implementation process so that it can be scaled up successfully in other sites. In addition, this project will build a program of study for trainees in a variety of disciplines who are interested in healthy lifestyles, chronic disease self-management, integrated approaches to care, and research methods, among others. Training students will help advance their careers as well as the research program itself.

The proposed healthy lifestyles program follows an ecological approach to health behavior where influences are looked at from individual, interpersonal, institutional or organizational, community and policy levels. Participants will identify barriers and facilitators at each of these levels, and these findings will be used to inform community efforts and stakeholder dialogues where policy implications will be considered.

APPROACHES AND METHODS

Methods

A pragmatic mixed methods design including a randomized controlled trial and qualitative components will be used for the study. This study will have elements of concurrent and embedded mixed methods designs. A mixed methods design allows for both quantitative and qualitative data to be collected, analysed and interpreted to understand various aspects of the program or intervention better, while also allowing for different research questions to be asked that require different types of data (i.e., quantitative or qualitative) that link up at multiple points of the study. (41) Specifically, concurrent data collection will answer the mixed methods research questions around program evaluation, such as “is the program meeting its objectives,” which include process, and short-term indicators. The embedded design will allow for qualitative data to be collected to add depth to the quantitative empirical findings, to answer questions around the process of implementing the programs, and to test and inform the programs. (42)

The randomized controlled trial will include a 1:1 allocation comparing MIP (usual care + healthy lifestyles program) vs. LIP (usual care + development of health goals). It is not blinded as the amount of exposure to the programs will be known to participants and providers. This study is pragmatic in that it is being conducted in a real-life setting with few criteria for exclusion, which allows for a wider range of participants to be studied. (38) This is important given the person-centered focus of these programs and multiplicity of participant-identified priorities and individualized possible outcomes. Having this ability to include a wider range of participants will allow for increased generalizability of the findings. (38) One challenge of pragmatic trials is that they need to be large enough to detect treatment effects given the large variation in the participants. This study proposes a first stage that examines the concept itself (i.e., the intervention), and the feasibility and implementation of the intervention. These findings will, in turn, inform other stages of the study and the evaluation of a larger, scaled-up, intervention. For example, sample sizes will be determined for a randomized controlled trial based on effect sizes found through this pilot phase.

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

other healthcare providers, along with participant satisfaction surveys every three months, to be used to make changes to the programs, or their delivery, while the study continues. Any key changes will be noted in the final report. If changes impact the conduct of the study, amendments will be made for ethics approvals and reported through ClinicalTrials.gov.

Setting and participants

This study will be conducted through McMaster University, and the site of the study will be at the David Braley Health Sciences Centre, Hamilton, Ontario. This site currently houses family physician offices and student classrooms, with accessibility considerations, including elevators and automatic doors. It is in a centrally located part of Hamilton with access through car and bus routes. The required office and meeting spaces are available.

Participants in the randomized trial will include English-speaking individuals 18 years of age or older. Because this phase incorporates group sessions, it is important to test the program concept with individuals who are able to engage in these sessions. Participants will also need to understand and sign the informed consent form.

Participants in qualitative components

Exit interviews will be conducted with participants at 12 months. MIP staff (family physician, dietician, physical therapist, administrative assistant) who are involved in running the healthy lifestyles program will be recruited for staff interviews at 6 months and 12 months. Healthcare providers involved in the participant's care outside of the study and identified by participants, with consent given to share information, will be approached to participate in semi-structured interviews at 6 months and 12 months. Family focus groups will include family members, who are 16 years of age or older and English-speaking, of participants in the MIP group.

Sampling and recruitment

Up to 15 participants will be recruited for each arm of the randomized trial. This number accounts for ideal numbers of people involved in small group sessions (8-15) based on practice experience and for potential attrition throughout the year. Effect size determination and other variables found from this study will be used to guide the sampling approach and sample size for further studies.

Initial recruitment for the randomized trial will occur at doctors' offices in the Hamilton area. Outreach to physicians will include a description of the programs and of this study. Posters will be placed in their office with the consent of the staff. (Appendix 1. Recruitment poster) The doctors' willingness to recommend the programs and number of participants recruited will determine the number of offices needed for recruitment. These outreach efforts are already in progress. (See letters of support) The posters contain contact information for the research assistant and a link to the healthy lifestyles program website (www.hlirc.com). PowerPoint slides will be provided to offices to show on their waiting room screens, if willing (Appendix 20). In addition, potential participants will be approached by a research assistant and/or student researcher during an office visit (as coordinated with the clinic staff), who will describe the purpose of the study and answer participant questions. The website will provide only information about the research study and how to contact the research assistant prior to the program starting. Following recruitment, the website may then be used to update participants of upcoming events or to add links to sources of information. No personal information or results from the study will

be published on the website. A Twitter account will be set up linked to the website to reach a broader audience, however, any information will only advertise the research study as already approved on the poster. Following recruitment, the Twitter account may then be used to update participants of upcoming events. No personal information or results from the study will be published through Twitter. If these recruitment efforts do not attain enough numbers of participants, posters will be placed in community settings, such as community centres, office buildings, etc. after obtaining consent from that facility. In addition, an advertisement will be placed in the Hamilton Spectator and in 'Coffee News' – both local media outlets. (See appendix 20)

The research assistant and/or student researcher will obtain consent and enroll participants into the study. (Appendix 2. Participant informed consent) Healthcare professionals involved with routine participant care or with the conduct of the programs will not be directly involved in enrolling participants into the study or obtaining informed consent. A participant maintains the right to drop out of the study at any time without consequences to her/his care. However, the numbers and reasons for dropping out of the study will be sought and noted as part of the program evaluation. Each participant will receive \$30 each time data is collected through a meeting with the research assistant every three months (five times total).

Sampling and recruitment for qualitative components

All participants will partake in a semi-structured exit interview during their last data collection meeting at 12 months. (Appendix 3. Participant interview guide) All MIP staff and health professionals involved in the participant's care outside of the study and identified by participants (for participants in both arms), with consent given to share information, will be approached face-to-face or by email or phone by a research assistant to participate in semi-structured interviews at 6 months and 12 months. Through the participants, family members (16 years of age or older, and English-speaking) will be asked to participate in up to two family focus groups with 6-10 people each at 9 months. Participants in the family focus groups will be provided with \$20 each. Informed consent will be obtained prior to the interviews or focus groups. (Appendices 4-9. Informed consent forms and interview/focus group guides) In addition, all relevant documents pertaining to the setting up and running of the programs will be reviewed.

Allocation and randomization

As participants are recruited for the randomized trial, they will be provided with a six digit ID number. Once 30 participants have been obtained, an Excel sheet will be created with just the ID numbers, and each one will be assigned a random number using the RAND function on Excel. Based on this randomization, participants will be allocated to the MIP or to the LIP in a ratio of 1:1, starting with the lowest number. The only change will occur if there are two or more participants who happen to be in a relationship and this is known to the research assistant. In this case, these participants will be placed in the same group based on who is randomized by the lowest number.

Neither the participants nor the health providers will be blinded to the intervention. A research assistant not involved in the recruitment or in the programs will allocate the participants, as described. Once allocation has occurred, names will be revealed to the same research assistant and s/he will notify participants of their allocation and provide further instructions and scheduling information. MIP staff and the research assistant/student researchers involved in collecting data will not be aware of the allocation of participants until the start of the

sessions. Participants will fill out a registration form at the first session. (Appendix 10. Registration form) This form includes the participant's contact information, emergency contacts and consent for sharing of information with their primary care provider.

Data collection procedures

Paper-based and/or electronic measures will be used to collect data. Please see Table 2 for a list and description of instruments used in the pilot study. A standardized data collection form (Appendix 11. Data collection form) will be used by a research assistant to gather information. For the MIP arm, charts will be reviewed when possible to gather data, such as the initial assessment, action plans, labs and measurements. The rest of the data for the MIP arm and all the data for the LIP arm will be collected through face-to-face individual meetings. The meetings for the MIP arm participants will be set up to be concurrent with follow-up visits to minimize burden. The action plan (MIP group) and the data collection form (LIP group) are used to help participants identify health goals. With the support of the MIP team or the research assistant for the LIP group (all trained in theories of health behaviour), participants will identify relevant health goals and define how to measure these goals on a 1-7 scale, with 1 being the "worst case," 7 being the "best case," and 4 being the "middle". Therefore, the measurements will also be participant-relevant while allowing for a variety of goals to be measured, including mental health-related goals such as decreasing symptoms of depression and behavioural changes such as amounts of physical activity. In addition, scales for motivation, stages of change, and self-efficacy are included for each goal. (See Appendix 11. Data collection form) If labwork information is not available in either arm, participants will be asked to have labwork drawn if they meet current screening guidelines. For HgA1C and lipids, this includes being 40 years of age or older or having risk factors as outlined in the guidelines for diabetes and cardiovascular disease, respectively. (43,44) A complete blood count (CBC) will only be conducted if the participant has symptoms, such as fatigue, or a history of cancer, infections or blood disorders as determined by the clinicians involved in the study. Measurements include blood pressure, height, weight, BMI, waist circumference, waist:hip ratio, and Edmonton obesity scale (if relevant). (45)

Participant satisfaction and feedback will be assessed through surveys at 3 months, 6 months and 9 months and will be provided and collected by the research assistant. (Appendices 12 & 13. Patient satisfaction surveys) Weekly nutrition journals and physical activity journals will be provided to participants in the MIP arm through the group sessions every three months. A research assistant will photocopy these from the chart, black out the names and provide the participant ID number on the paper. For the LIP arm, these journals will be provided directly by and returned to the research assistant (Appendices 14 & 15. Nutrition and physical activity journals). In addition, a costs and medical utilization log will be provided to each participant in both arms and these will be collected by the research assistant every three months. (Appendix 16. Costs and medical utilization log) Worksheets for each health and wellness learning session will be provided for participants in the MIP group only. These will not be collected for study purposes but they do provide a space for reflection during and after each session.

For research purposes the pilot involves the use of two generic and a number of specific measures of health status and health-related quality of life. The routine application of the intervention would involve a more parsimonious set of measures. Validated health and wellbeing scales will be filled out by participants at baseline and every three months to assess change in these indicators (five times total). The MIP arm participants will fill these out during group sessions and the research assistant will obtain this information through chart review. The LIP

participants will fill out these scales during their meeting with a research assistant. The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) will only be filled out at baseline to ensure goals related to physical activity are appropriate given a participant's health status. Any concerns found through these or other scales will be relayed to the principal investigator and dealt with according to current practice and per the Good Clinical Practice guidelines for clinical trials. See also data monitoring section. The rest of these scales were selected for addressing a holistic range of mental health indicators that are dealt with in the healthy lifestyles program. The RAND SF-36 (46,47) and HUI 2/3 (48–50) are validated instruments for health-related quality of life indicators. The decision to use both is to compare findings from these instruments. The SF-36 has been used extensively in multiple settings and is readily available and free. However, there are some limitations concerning floor effects, which is why the HUI 2/3 has been suggested by collaborators. On the other hand, the HUI 2/3 is proprietary and not as readily accessible to health providers for use in practice. The Patient Health Questionnaire (PHQ) is made up of five domains to evaluate for depression (PHQ-9), anxiety (GAD-7), bulimia, somatoform disorders and alcohol misuse. (51–53) This scale was selected for general mental health indicators as it combines multiple related domains, has been used extensively for research and practice, and the components are used among family physicians in the Hamilton area (personal correspondence). Importantly, the PHQ-9 has also been found to be sensitive to change for monitoring of treatment outcomes. (54) The Insomnia Severity Index was identified as the most fitting validated scale to identify insomnia symptoms. (55) The Life Change Index Scale, otherwise known as the Holmes and Rahe stress scale, has been found to correlate with medical utilization in a family practice setting. (56) In addition, the Perceived Stress Scale measures the degree to which situations in one's life are perceived as stressful. (57,58) Lastly, the DeJong Gierveld 6-item Loneliness Scale captures both emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network). (59,60)

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

Data from all these forms will be entered into Research Electronic Data Capture (REDCap) (<https://www.project-redcap.org/>). All information will be kept confidential and participants IDs will be used whenever data is coded. A list of participant IDs and their associated names will be kept in separate locations. Paper documents will be kept in a locked cabinet on campus and any electronic information will be kept on password-protected computers. Only research team members will have access to the data. Data collection methods will be evaluated to determine if any changes need to be made for the following phase.

Qualitative data

The participants (at 12 months), MIP staff (at 6 months and at 12 months), and health providers (at 6 months and at 12 months) will be asked to participate in face-to-face semi-structured interviews. Family members will be asked to participate in focus groups (at 9 months). Informed consent will be obtained prior to conducting these interviews and/or focus groups. The interviews and focus groups will be recorded with a digital recorder and transcribed. Field notes will also be taken during these interviews and focus groups to describe the setting and keep track of other events. Recordings and transcriptions will be kept in locked cabinets and/or password-protected computers on campus. Documents related to the programs or their implementation will also be used as data.

Incentives

Incentives will be provided for participants in both arms, including \$30 for each time measurements are completed (baseline, 3 months, 6 months, 9 months, and 12 months). This amount is seen as a fair amount given the time spent on providing information or having bloodwork done (about an hour), but it is not an amount that would be considered coercive. The incentive will be given to the participant upon attendance at the meeting, not based on data completeness as this could be seen as coercive. Participants in the family focus groups will be provided \$20 for their participation.

Training of health professionals and research staff

The health professional leading the intervention is a family physician with training in medical CBT. In addition, she has developed and teaches a Theories of Health Behaviour course at McMaster University and has certificates of completion for the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics (TCPS 2: CORE)*, the *Tutorial for Researchers Conducting Retrospective Review of Health Records* (Certification #698149) and *Good Clinical Practice* for clinical trials (Record ID #22456269). The dietician and physical therapist are fully licensed. Research assistants and student researchers will have training on research ethics through the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics (TCPS 2: CORE)* and will also complete the *Tutorial for Researchers Conducting Retrospective Review of Health Records*. They will have training on how to interview participants to obtain data during individual meetings, on how to obtain proper measurements and how to answer questions relating to the scales, nutrition and physical activity journals, and the costs and medical utilization logs. Lastly, training will be provided on how to support participants in the LIP to identify goals. If they are involved in the qualitative components, more intensive training will be provided by the team on how to conduct participant interviews and focus groups, and how to maintain field notes. All team members will have training on confidentiality and handling of data as set out in this proposal. Facilitators for the brainstorming sessions will have training on how to lead facilitated sessions around healthy lifestyles and conflict management.

Table 2. Pilot study instruments

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

Data analysis*Quantitative*

See Table 3 for a description of the objectives of the study, outcomes measured, and analytic techniques for each component. Quantitative data will be reviewed for completeness and

entered into Excel and/or SPSS by the research assistant/student researchers. Missing data will be noted in order to evaluate the study instruments themselves. Descriptive statistics will be presented for the participants in the study. Changes within individuals over time, and differences within and between groups will be assessed. Regression and multivariate analyses will be conducted to the extent possible, realizing this pilot phase constitutes a small sample. Since this is a pilot study, this information will be looked at to help inform a larger randomized trial and statistical significance will not be sought. Total costs and cost-effectiveness analyses will also be conducted to the extent possible.

Qualitative

Transcripts, field notes, and documents will be entered into NVivo and coded. Concepts and themes will be developed using a constant comparative method of analysis in which new information is compared to previous information. Themes related to the concept of the programs, implementation of the programs and feasibility will be developed, among others. Confirming and disconfirming evidence will be sought to ensure data saturation or completeness of the findings. (61)

Integration of data

Integration of data will occur at various points. First, qualitative data will be used to understand the quantitative data in more depth. For example, adherence with particular aspects of the programs will be compared with themes developed from the qualitative data to understand what particular barriers impacted on adherence. In a similar fashion, qualitative data will be compared with effectiveness of the intervention (e.g., achieving goals) to understand what components may have led to success or non-success. These aspects will help evaluate the programs holistically and will provide insights for improving and scaling up the healthy lifestyles program.

Data and participant monitoring

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

Participants will fill out mental health scales, which will be scored during their visits. If any concerns around these findings or other signs of deterioration are encountered by anyone on the research or program teams, the principal investigator or alternate clinician will be notified while the participant is still in contact with the team member. An assessment will be conducted and if any concerns arise for self harm or harm to others, proper guidelines will be followed, including creating a safety plan (62), contacting the participant's family physician or providing more frequent follow-ups, or contacting emergency services, as deemed appropriate.

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

Table 3. Study objectives, outcomes and analysis plans

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

Knowledge translation

Knowledge translation activities will occur throughout the study. Whenever possible, a knowledge exchange process will be sought so that knowledge is pushed to the audience but also

different perspectives are invited to improve the evaluation of the Program and what is learned through the findings. Peer-reviewed publications and presentations at conferences will target researchers and health professionals. Policymakers and other stakeholders will be engaged throughout the process to identify needs and community/policy implications of these findings.

Timeline and activities (Appendix 17)

The pilot phase will take approximately 24 months. This includes time for registering the proposal as a clinical trial with ClinicalTrials.gov, obtaining ethics approval, setting up the logistics of the programs (e.g., recruiting a research assistant, booking rooms), recruiting participants, running the full programs and generating knowledge translation activities. Information from this study will be used to improve the healthy lifestyles program, to test the logistics of running the healthy lifestyles program at capacity and to assess the conditions for a larger randomized controlled trial with the healthy lifestyles program running at full capacity.

Budget

The expected research budget is \$363,500 CAD. (Appendix 18. Research budget) This includes a full time research assistant, part time biostatistician, and thesis and practicum students. This also includes consumables such as paper and toner, analytic software, transcription services, incentives for participants, child minders and snacks for the interviews and focus groups. The budget also allocates money towards knowledge translation activities such as publishing in open-access peer-reviewed journals and presenting at conferences. In-kind contributions from McMaster University include \$26,000 for students and overhead. Remaining needs are **\$337,500**.

The cost of running the programs for the pilot phase is expected to be \$109,700. Funding for the programs has been secured, mainly through in-kind contributions from McMaster University and from team members.

Potential challenges

Ethical considerations

The study protocol will be submitted to the Hamilton Integrated Research Ethics Board (HIREB). In addition, the study will be registered as a clinical trial with ClinicalTrials.gov. A research assistant will approach potential study participants to explain the nature of the study, their rights as study participants, confidentiality of their data, voluntary entry into the study, and their ability to withdraw from the study at any time. (63,64) There is minimal risk of entering this study, however, participants will be informed about the potential risks of unintended disclosure, where they may potentially give away information about themselves or about a third party which could lead to recognition of themselves or the third party (in which case confidentiality will be sought for the third party as well). In addition, there are some risks to starting or increasing any exercise activity, such as injury. However, the benefits of increasing mobility outweigh most of the risks of potential injury and having trained team members and setting realistic goals will allow for gradual adjustments in their mobility levels. Any questions will be answered, and informed consent will be obtained prior to enrolling any participant into the study. All data gathered for the study will be kept confidential by using identifiers (with identifiers and identifying data kept separately), and access will only be given to the research team members. Paper documents will be stored in a locked cabinet on campus. Electronic documents will be kept on computers at McMaster, all with password access.

Incentives – Participants will receive \$30 each time they meet with the research assistant for data collection every three months (5 times total). These amounts are seen as valid, but not

coercive, for the amount of work involved. Control-arm participants (less intensive program) will be allowed to participate in the healthy lifestyles program (MIP) at a later date on the condition that the program is still running.

If any changes are made to the research design, HIREB will be notified and changes will be made based on their recommendations.

Scientific, technical or organizational considerations

The main challenge with the proposed healthy lifestyles program is that the components are not traditionally covered by the current funding model in Ontario. While the physician components could be billed under OHIP, this billing would be considered ‘counseling’ under OHIP guidelines, and these fees are not comparable with fees charged for acute care diagnoses. In addition, dietician counseling and physical therapy are not generally covered services, except for specific diagnoses. Over-the-phone dietician services are offered for free in Ontario, however, there is no guaranteed continuity of care. Combining these services to provide holistic and team-based care is the purpose of this study. These funding considerations are critical for the sustainability of the healthy lifestyle programs, both during these pilot phases and in scaling up. On-going funding considerations will be drawn from cost-effective analysis through the larger randomized trial that will be informed by this pilot study.

RESEARCH TEAM

Team’s expertise and experience

The team is comprised of researchers, health professionals, knowledge users and patients/stakeholders. Methodologically, the team has experience in quantitative, qualitative and mixed methods research. Combined, the team has experience developing and carrying out clinical trials, from conception to write-up. The team’s content expertise spans many fields, including medicine, public health, health promotion, mental health, physical therapy, nutrition, eHealth, health systems and policy, knowledge translation, and health economics.

Team’s level of engagement and commitment (Appendix 19)

Principal investigator - Dr. Elizabeth Alvarez – 14 hrs/week - manage all aspects of the research including human resources, funding and project completion. Helps research coordinator in identifying priorities and opportunities, especially with regards to qualitative data collection and analysis and mixed methods interpretation. Supervise students in multiple health-related fields. In addition, Dr. Alvarez is a certified family physician, so any medical concerns that arise during the study can be addressed. Because of her dual role in the MIP and in monitoring the research, any enrollment of participants into the study or gathering of informed consent will be carried out by a research assistant. In addition, qualitative data will be gathered by a research assistant and/or student investigator, and participant IDs will be assigned to any data by the research assistant prior to data analysis.

Co-investigators

Dr. Lawrence Mbuagbaw – 4 hrs/week – assist with project management, especially as it relates to quantitative data collection and analysis and mixed methods interpretation. Supervise students in health research methods.

Dr. Majdi Qutob – 4 hrs/week – assist with project management, especially as it relates to data management and administrative issues.

Dr. Cynthia Lokker – 4 hrs/week – assist with all aspects of the research as needed, especially as it relates to eHealth initiatives and data management. Supervise students in eHealth.

Ms. Marjan Walli-Attai – 4 hrs/week – assist with all aspects of the research as needed, especially with regards to economic analyses and health policy. She is a doctoral candidate in health policy with a concentration in health economics at McMaster University.

Dr. Zena Samaan – 2hrs/week – assist with all aspects of the research as needed, especially as it relates to mental health and data management. She is a clinician-researcher in Psychiatry and Behavioural Neurosciences with experience in pragmatic clinical trials involving mental health programs.

Dr. John Lavis – 2 hrs/month – assist with knowledge translation activities and provide ongoing feedback on activities. Supervise students in health policy and other health-related fields. Dr.

Lavis is the Canada Research Chair in Evidence-Informed Health Systems.

Multiple other collaborators are engaged in this study (Appendix 19). Collaborators have helped shape this proposal and are available for questions throughout the study and in the interpretation of the results but are not involved in data collection or the conduct of the analysis.

Research environment

McMaster University provides a rich and supportive environment to conduct health-related research. The facilities (e.g., David Braley Health Sciences Centre, offices), infrastructure (e.g., access to the university library), support personnel (e.g., administrative support), equipment (e.g., computers), and supplies (e.g., printer, paper) will allow each researcher to carry out his/her role for this proposed project.

Appropriateness of the research team in relation to achieving stated goals, meaningful inclusion of participants, healthcare professionals and policymakers

The research team comprises researchers, healthcare professionals, knowledge users, and patients/stakeholders, who have all provided input into the healthy lifestyles program and/or the evaluation of the program. Two patients/stakeholders have been involved in the development of this proposal. In addition, participants' perspectives will be sought throughout the study especially with regards to implementation considerations and with regards to program evaluation. Program staff and participants' health providers will also be included in evaluating the program and its implementation through qualitative in-depth interviews. Family members of participants in the MIP arm will be invited to participate in focus groups to gain insight into the role of family members in creating and maintaining healthy lifestyles and their perspectives on the MIP. Dissemination of findings will also occur through presentations at conferences and for community and health professional groups, publishing of findings in peer-reviewed journals and in reports, and through direct communication with other researchers, community and special interest groups (e.g., community pharmacists, pharmaceutical companies), and policymakers.

ENGAGEMENT AND PARTNERSHIP

Partnership building activities and plans to attain sustainable relationships

The intent of the healthy lifestyles program is to help participants develop realistic and sustainable healthy lifestyle plans. Following the ecological model for health behavior, these plans will not only include individual but also interpersonal, community or organizational, and policy aspects of healthy lifestyles. To address these perspectives, further partnerships will be

sought with relevant community groups/individuals to support the participants' healthy lifestyle changes. In addition, outreach to relevant decision-makers will be conducted to disseminate findings from the study but also to engage them on determining policy implications of the program especially with regards to a larger randomized trial. To meet these ends, more formal partnerships will also be sought at the regional level with public health and local health integration networks (LHIN) and with other researchers at McMaster University. One of the co-applicants on this proposal is the Director of the McMaster Health Forum at McMaster University. The Forum works with citizens, policymakers and other stakeholders to support the use of research evidence in health decision-making. At a national level, links with the Pan-Canadian SPOR Network in Primary and Integrated Health Care Innovations will be invaluable and membership into this Network will be sought.

Engagement plan

Because families and communities are an integral part of an individual's abilities to make healthy lifestyle changes, they will be included in both evaluation as well as treatment aspects of the MIP. For example, with the participant's permission, their families will be asked to partake in evaluation activities to understand their perspectives around issues of healthy lifestyles and chronic disease prevention and management. Community supports will be identified from the perspective of participants' needs. Principles of community engagement (39,65,66) will be followed but modifications may be made as these approaches may necessitate new methods since the starting point is not the community, but rather, the individual and his/her needs. Links with health units and LHINS in Southern Ontario already exist through the McMaster Master of Public Health Program's educational and practicum activities. These relationships will be strengthened through meetings and collaborations arising through this project. Membership into the Pan-Canadian SPOR Network in Primary and Integrated Health Care Innovations will help engage the larger Network, and collaborations with those working on integrating care and healthy lifestyles can be developed.

MENTORING AND TRAINING

Proposed actions to mentor and train junior team members in the conduct of participant-oriented research

Research team members will receive training in conducting data collection in participant-oriented research. In addition, a number of practice-based students (e.g., clinical, public health, nursing, physician assistants) will be able to train in person-centered care as well as participant-oriented research. Thesis and research practicum students will be able to help with patient recruitment, data collection and analysis, project management and related research activities. The adaptive design of this study, will allow trainees will have the opportunity to partake in this study and develop sub-studies to be conducted in a larger randomized trial or for future research. For example, eHealth students may take on reviewing and testing various wearable technologies for managing stress or for increasing physical activity. Public health students will be able to test innovative approaches to health promotion. Physician assistant students may be able to test their roles within a multidisciplinary approach to healthy lifestyles. If these projects are not already reflected in this proposal, additional project proposals will be submitted to HIREB prior to commencement of the projects.

REFERENCES

1. Senate Canada. Obesity in Canada; A Whole-of-Society Approach for a Healthier Canada [Internet]. Report of the Standing Senate Committee on Social Affairs, Science and Technology; 2016 Mar. Available from: www.senate-senat.ca/social.asp
2. WHO. Obesity and overweight [Internet]. WHO. 2016 [cited 2016 Sep 8]. Available from: <http://www.who.int/mediacentre/factsheets/fs311/en/>
3. Choban MD F Patricia S, Flancbaum MD F Louis. The Impact of Obesity on Surgical Outcomes: A Review. *J Am Coll Surg*. 1997 Dec;185(6):593–603.
4. Canadian Obesity Network. Obesity in Canada [Internet]. [cited 2016 Sep 8]. Available from: <http://www.obesitynetwork.ca/obesity-in-canada>
5. Mehrotra C, Remington PL, Naimi TS, Washington W, Miller R. Trends in total knee replacement surgeries and implications for public health, 1990-2000. *Public Health Rep*. 2005 Jun 5;120(3):278–82.
6. Goodman B. Obesity Puts Young Kids at Risk of Social Isolation [Internet]. WebMD. [cited 2016 Sep 8]. Available from: <http://www.webmd.com/children/news/20110916/obesity-puts-young-kids-at-risk-of-social-isolation>
7. El Nakeeb A, Hamed H, Shehta A, Askr W, El Dosoky M, Said R, et al. Impact of obesity on surgical outcomes post-pancreaticoduodenectomy: A case-control study. *Int J Surg*. 2014 May;12(5):488–93.
8. Liu W, Wahafu T, Cheng M, Cheng T, Zhang Y, Zhang X. The influence of obesity on primary total hip arthroplasty outcomes: A meta-analysis of prospective cohort studies. *Orthop Traumatol Surg Res OTSR*. 2015 May;101(3):289–96.
9. Holiday Retirement. Studies connect socializing with quality of life | Senior Living Articles [Internet]. [cited 2016 Sep 10]. Available from: <http://www.holidaytouch.com/retirement-101/senior-living-articles/socializing-linked-with-quality-of-life>
10. CBC News. Socializing key to “successful aging” - Health [Internet]. [cited 2016 Sep 10]. Available from: <http://www.cbc.ca/news/health/socializing-key-to-successful-aging-1.1260922>
11. Beck J. *The Beck Diet Solution*. Birmingham, Alabama: Oxmoor House, Inc.; 2007.
12. Gibbons CJ, Fournier JC, Stirman SW, DeRubeis RJ, Crits-Christoph P, Beck AT. The clinical effectiveness of cognitive therapy for depression in an outpatient clinic. *J Affect Disord*. 2010 Sep;125(1–3):169–76.
13. Porto PR, Oliveira L, Mari J, Volchan E, Figueira I, Ventura P. Does cognitive behavioral therapy change the brain? A systematic review of neuroimaging in anxiety disorders. *J Neuropsychiatry Clin Neurosci*. 2009;21(2):114–25.
14. Chesson AL, Anderson WM, Littner M, Davila D, Hartse K, Johnson S, et al. Practice parameters for the nonpharmacologic treatment of chronic insomnia. *An American Academy of Sleep Medicine*

- report. Standards of Practice Committee of the American Academy of Sleep Medicine. *Sleep*. 1999 Dec 15;22(8):1128–33.
15. Canadian Medical Association. CMA Position Statement: Ensuring Equitable Access to Care: Strategies for Governments, Health System Planners, and the Medical Profession.
 16. Warren M. Mental health wait times a serious problem across Ontario, say advocates | Metro News. *metronews.ca* [Internet]. 2016 Jun 21 [cited 2016 Sep 10]; Available from: <http://www.metronews.ca/news/toronto/2016/06/21/mental-health-wait-times-not-just-a-problem-in-small-communities.html>
 17. Armstrong L. Ontario youth wait a year or more for mental health care: report | Toronto Star. *Toronto Star* [Internet]. 2015 May 5 [cited 2016 Sep 10]; Available from: https://www.thestar.com/life/health_wellness/2015/05/05/ontario-youth-wait-a-year-or-more-for-mental-health-care-report.html
 18. Ontario Ministry of Health and Long-Term Care. Patients First: A Proposal to strengthen patient-centred health care in Ontario. Discussion Paper [Internet]. Queen's Printer for Ontario; 2015 Dec. Report No.: Catalogue no. 020380 ISBN no. 978-1-4606-7171-9. Available from: file:///C:/Users/Owner-PC/AppData/Local/Temp/discussion_paper_20151217.pdf
 19. PICARD A. Taking patient-centred health care from rhetoric to reality. 2016 Jul 22 [cited 2017 Jul 15]; Available from: <https://www.theglobeandmail.com/life/health-and-fitness/health/taking-patient-centred-care-from-rhetoric-to-reality/article31077949/>
 20. Government of Ontario M of H and L-TC. The Patients First Act - Frequently Asked Questions [Internet]. [cited 2017 Jul 15]. Available from: http://www.health.gov.on.ca/en/news/bulletin/2016/hb_20161207_faq.aspx
 21. Resnicow K, Dilorio C, Soet J, Borrelli B, Hecht J, Ernst D. Motivational interviewing in health promotion: It sounds like something is changing. *Health Psychol*. 2002;21(5):444–51.
 22. Sherman M, Miller L, Keuler M, Trump L, Mandrich M. Managing behavioral health issues in primary care: 6 five-minute tools. *Fam Pract Manag*. 2017 Apr;31–5.
 23. McKeon P, McKeon J. Evidence-Based Practice or Practice-Based Evidence: What's in a Name? *Int J Athl Ther Train*. 2015;20(4):1–4.
 24. Bartholomew LK, Parcel GS, Kok G, Gottlieb NH, Fernandez ME. Planning health promotion programs: An intervention mapping approach. San Francisco, CA: Jossey-Bass; 2011.
 25. McLeod SA. Maslow's Hierarchy of Needs [Internet]. 2014. Available from: www.simplypsychology.org/maslow.html
 26. Dawson P, Guare R. Coaching students with executive skills deficits. New York, NY: The Guilford Press; 2012.
 27. Dubord G. Cognitive Behavioural Therapy (CBT) for anxiety. 2015; Blue Mountain, ON.

28. Dubord G. Cognitive Behavioural Therapy (CBT) for depression. 2015; Ottawa, Canada.
29. Dubord G. Cognitive Behavioural Therapy (CBT) tools. 2015; Toronto, ON.
30. Dubord G. Part 1. Goalification. Can Fam Physician. 2010 Dec 1;56(12):1312–1312.
31. Dubord G. Part 2. Scalification. Can Fam Physician. 2011 Jan;57:54.
32. Prochaska J, DiClemente C. Stages and Processes of Self-Change of Smoking: Toward An Integrative Model of Change. J Consult Clin Psychol. 1983;51(3):390–5.
33. prochaska and diclemente’s stages of change model - Google Search [Internet]. [cited 2017 Apr 5]. Available from:
https://www.google.ca/search?q=prochaska+and+diclemente%27s+stages+of+change+model&ie=utf-8&oe=utf-8&gws_rd=cr&ei=U__kWM3gDsqrjwTq1ZT4Dg
34. Abrams DB, Orleans CT, Niaura RS, Goldstein MG, Prochaska JO, Velicer W. Integrating individual and public health perspectives for treatment of tobacco dependence under managed health care: A combined stepped-care and matching model. Ann Behav Med. 1996 Fall;18(4):290–304.
35. Alvarez E. Stress management. 2015 Apr 7; McMaster University.
36. Alvarez E. Time management. 2015 Apr 14; McMaster University.
37. Samaan Z, Litke K, McCabe K, Dennis B, Whattam J, Garrick L, et al. A pragmatic pilot randomized trial to investigate the effectiveness of behavioural activation group therapy in reducing depressive symptoms and improving quality of life in patients with depression: the BRAVE pilot trial protocol. Pilot Feasibility Stud. 2015 Nov 10;1:39.
38. Patsopoulos NA. A pragmatic view on pragmatic trials. Dialogues Clin Neurosci. 2011 Jun;13(2):217–24.
39. Thabane L, Kaczorowski J, Dolovich L, Chambers LW, Mbuagbaw L. Reducing the confusion and controversies around pragmatic trials: using the Cardiovascular Health Awareness Program (CHAP) trial as an illustrative example. Trials. 2015;16:387.
40. Creswell J, Plano Clark V. Designing and conducting mixed methods research. 2nd ed. Washington DC: Sage Publications, Inc.; 2011.
41. Feters MD, Curry LA, Creswell JW. Achieving Integration in Mixed Methods Designs—Principles and Practices. Health Serv Res. 2013 Dec;48(6 Pt 2):2134–56.
42. Zhang W. Mixed methods embedded design in medical education, mental health and health services research: A methodological analysis. ETD Collect Univ Neb - Linc Pap AAI3487306 [Internet]. 2011 Jan 1; Available from: <http://digitalcommons.unl.edu/dissertations/AAI3487306>
43. Diabetes Canada | Clinical Practice Guidelines - Chapter 4: Screening for Type 1 and Type 2 Diabetes [Internet]. [cited 2017 Jul 23]. Available from:
<http://guidelines.diabetes.ca/browse/chapter4>

44. Anderson TJ, Grégoire J, Pearson GJ, Barry AR, Couture P, Dawes M, et al. 2016 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult. *Can J Cardiol*. 2016 Nov 1;32(11):1263–82.
45. Padwal RS, Pajewski NM, Allison DB, Sharma AM. Using the Edmonton obesity staging system to predict mortality in a population-representative cohort of people with overweight and obesity. *CMAJ Can Med Assoc J*. 2011 Oct 4;183(14):e1059.
46. Monica 1776 Main Street Santa, 90401-3208 C. 36-Item Short Form Survey (SF-36) | RAND [Internet]. [cited 2017 Jul 22]. Available from: https://www.rand.org/health/surveys_tools/mos/36-item-short-form.html
47. Brazier JE, Harper R, Jones NMB, O’Cathain A, Thomas KJ, Usherwood T, et al. Validating The SF-36 Health Survey Questionnaire: New Outcome Measure For Primary Care. *BMJ*. 1992;305(6846):160–4.
48. HUI Update [Internet]. [cited 2017 Jul 22]. Available from: <https://fhs.mcmaster.ca/hug/update.htm>
49. Sheffield U of. UK Valuation - HUI2 - Measuring & Valuing Health - HEDS - Sections - SchARR - The University of Sheffield [Internet]. [cited 2017 Jul 22]. Available from: <https://www.sheffield.ac.uk/scharr/sections/heds/mvh/hui2>
50. Marshall D, Pericak D, Grootendorst P, Gooch K, Faris P, Frank C, et al. Validation of a Prediction Model to Estimate Health Utilities Index Mark 3 Utility Scores from WOMAC Index Scores in Patients with Osteoarthritis of the Hip. *Value Health*. 2008 May 1;11(3):470–7.
51. Kohrt BA, Luitel NP, Acharya P, Jordans MJD. Detection of depression in low resource settings: validation of the Patient Health Questionnaire (PHQ-9) and cultural concepts of distress in Nepal. *BMC Psychiatry*. 2016 Mar 8;16:58.
52. phqscreeners [Internet]. phqscreeners. [cited 2017 Jul 23]. Available from: <http://www.phqscreeners.com/>
53. Seo J-G, Park S-P. Validation of the Generalized Anxiety Disorder-7 (GAD-7) and GAD-2 in patients with migraine. *J Headache Pain* [Internet]. 2015 [cited 2017 Jul 23];16. Available from: </pmcc/articles/PMC4656257/?report=abstract>
54. Lowe B, Unutzer J, Callahan C, Perkins A, Kroenke K. Monitoring depression treatment outcomes with the Patient Health Questionnaire-9. *Med Care*. 2004;42:1194–201.
55. Validation of the Insomnia Severity Index as an outcome measure for insomnia research - ScienceDirect [Internet]. [cited 2017 Jul 23]. Available from: <http://www.sciencedirect.com.libaccess.lib.mcmaster.ca/science/article/pii/S1389945700000654>
56. Lynch D, McGrady A, Alvarez E, Forman J. Recent Life Changes and Medical Utilization in an Academic F... : The Journal of Nervous and Mental Disease. *J Nerv Ment Dis*. 2005;193(9):633–5.

57. Siqueira Reis R, Ferreira Hino AA, Romélio Rodriguez Añez C. Perceived Stress Scale: Reliability and Validity Study in Brazil. *J Health Psychol.* 2010 Jan;15(1):107–14.
58. Leung DY, Lam T, Chan SS. Three versions of Perceived Stress Scale: validation in a sample of Chinese cardiac patients who smoke. *BMC Public Health* [Internet]. 2010 Dec [cited 2017 Jul 23];10(1). Available from: <http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-10-513>
59. Gierveld JDJ, Tilburg TV. A 6-Item Scale for Overall, Emotional, and Social Loneliness: Confirmatory Tests on Survey Data. *Res Aging.* 2006 Sep;28(5):582–98.
60. Grygiel P, Humenny G, Rebisz S. Using the De Jong Gierveld Loneliness Scale With Early Adolescents: Factor Structure, Reliability, Stability, and External Validity. *Assessment* [Internet]. 2016 Dec 8 [cited 2017 Jul 23]; Available from: <http://asm.sagepub.com/cgi/doi/10.1177/1073191116682298>
61. Creswell J. *Qualitative inquiry & research design: Choosing among five approaches.* Thousand Oaks, CA: Sage; 2007.
62. Centre for Addiction and Mental Health (CAMH). CAMH suicide prevention and assessment handbook. Canada; 2015 p. 87. Report No.: ISBN: 978-1-77052-860-4 (PDF).
63. Government of Canada IAP on RE. Interagency Advisory Panel on Research Ethics [Internet]. 2014 [cited 2016 Sep 12]. Available from: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
64. Yin R. *Case Study Research: Design and Methods.* 4th ed. Thousand Oaks, CA: Sage; 2009.
65. Horowitz CR, Mimsie Robinson R, Seifer S. Community-Based Participatory Research from the Margin to the Mainstream: Are Researchers Prepared? *Circulation.* 2009 May 19;119(19):2633–42.
66. Anderson JB. Unraveling health disparities: Examining the dimensions of hypertension and diabetes through community engagement. *J Health Care Poor Underserved.* 2005;16(4A):91–117.