RESEARCH PROTOCOL

BETTER HEALTH: DURHAM

BETTER = Building on Existing Tools To Improve Chronic Disease Prevention and Screening

Funded as a research grant entitled: Advancing Cancer Prevention in Deprived Neighbourhoods

Funding agencies: Canadian Cancer Society Research Institute and

Canadian Institutes for Health Research, Institute of Cancer

Canadian Cancer Society Research Institute grant #704042

Canadian Institutes for Health Research Institute of Cancer OCP #145450

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version Jan 30, 2017

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1.0 INTRODUCTION TO BETTER HEALTH: DURHAM

1.0 *Introduction*: *chronic disease prevention and screening*

Smoking cessation, healthy diet, sufficient physical activity, reduction / elimination of alcohol use reduce the risk of developing and dying from cancers, diabetes, and circulatory diseases[8]. Cervical and colorectal cancer screening prevent the evolution of precursor lesions to invasive cancer and detect invasive cancers at localized stages, leading to decreased cancer-related mortality[9,11]. Mammography may reduce breast cancer related mortality[10].

1.1 *Chronic disease screening in deprived areas*

We recently studied persons eligible for breast, colorectal, cervical, glucose, and / or lipid screening, and the percent of eligibles with recent participation, in all dissemination areas (referred to as 'small areas', n= 18,950) in Ontario[18]. Colorectal, breast, cervical, glucose and lipid screening are lowest in low income areas, especially among those without a regular **P**rimary **C**are **P**hysician (PCP)[18,54b].

Table 1: Screening participation rates by median household income quintiles in Ontario

Quintile of median household income	Colorectal	Breast	Cervical	Glucose	Lipids
Highest quintile overall	64.6%	68.6%	76.5%	69.2%	85.5%
Lowest quintile with regular PCP	51.3%	56.1%	63.3%	67.1%	83.1%
Lowest without regular PCP	9.7%	8.7%	12.1%	8.6%	23.25%

Among low income clusters, a significant proportion of persons aged 40 - 64 years who have not yet developed circulatory, diabetic, or cancer morbidity, do not receive primary care, from one year to the next. Among these small areas, the median for enrollment by females in a Patient Enrollment Model PCP[54b] (whether or not they are able to see that physician) is only 72.1% (interquartile range IQR 67.9% - 74.4%) and by males is 60.9% (IQR 56.6 - 63.4)[18], compared to 86% (IQR 81% - 91%) overall for all females and 83% (IQR 76 - 88%) overall for all males[18]. Low income is **not** the only factor associated with disparities in preventive and screening activities, and poor health outcomes, but it is **the most common**, negatively affecting many of the 1,320,000 premorbid persons aged 40 - 64 living in the lowest income quintile[18].

1.2 *Promotion of preventive behaviours, and activities (including screening) in Ontario*

In general, chronic disease preventive and screening behaviours are promoted as discrete, 'stand-alone' activities, as opposed to an integrated set of **C**hronic **D**isease **P**reventive and **S**creening actions (**CPDS**)[22]. Screening for cervical, colorectal, and breast cancer (and their risks), and assessment and screening for cardiovascular and diabetes risk factors, occur mainly in primary care, with minimal programmatic facilitation of participation (CancerCareOntario invitations to cervical and colorectal screening instruct the person to attend their regular PCP[11b], which is impossible for those who have not had a regular PCP). By regular PCP, we mean a PCP whom a person is able to consult periodically, and

who is the same physician seen at the majority of medical non-specialist visits during the previous two years[54b].

Despite major increases in funding for PCPs and Patient Enrollment Models of Practice, and financial incentives to PCPs for cancer screening, participation in cancer screening has not improved[28,32]. For those in low income clusters, having to attend a PCP office may be a barrier, because of impaired access to PCPs[18], which has not been ameliorated by these strategies. Although community health centres target those with multiple morbidities in low income clusters, and although Family Health Teams receive funds for preventive activities, these strategies have not had an impact on screening rates among low income clusters overall [5,18].

1.3 *Addressing low overall participation in Chronic Disease Preventive and Screening (CDPS) actions by the 'BETTER' Prevention Practitioner Intervention*

The 'BETTER' prevention practitioner intervention[3,22] was designed with several goals: to integrate the approach to **CDPS** actions[22], to optimize participation in **CDPS** actions, in primary care practices[22], and to create a feasible, evidence-based intervention[8] to motivate individual 40 - 64 year-old persons to undertake **CDPS** actions for which they are eligible but not currently undertaking[22]. The 'BETTER' prevention practitioner intervention involves assessment of a person's current participation, or lack of participation, among domains of evidence-based **CDPS** actions by a research assistant. The assessment is followed several days later by a supportive meeting with a prevention practitioner nurse, using principles of shared decision making, health coaching, and brief action planning as mode of interviewing, to establish goals for accomplishing **CDPS** activities of the individual's choice during the subsequent six months.[22,42, 44,55, 57] to develop personal goals and targets for participating in **CDPS** actions during the following six months. In BETTER HEALTH: DURHAM, the prevention practitioner nurse will be a public health nurse from the Durham Region Health Department.

The original 'BETTER' cluster randomized trial compared the outcomes of the **'BETTER'** prevention practitioner intervention at the individual patient level within allocated clusters of PCPs in Family Health Teams, to patients who did not receive the intervention. In the adjusted analysis, control patients met 23.1% (95% CI: 19.2% to 27.1%) of target actions, compared to 55.6% (95% CI: 49.0% to 62.1%) receiving the patient-level intervention p< 0.001).[22] This result was replicated in an implementation study[42] among primary care practices in communities in Newfoundland and North West Territories[23,42]; that study reveals how contextual factors influence implementation[42].

2.0 GOAL of BETTER HEALTH: DURHAM

The goal of this proposal is to improve participation in **CDPS** actions in low income clusters in Durham Region, by implementing the **'BETTER'** prevention practitioner intervention, in the community setting rather than in a medical practice setting, among persons in low income clusters characterized by the lowest quintile of median household income and with lowest participation rates in cancer screening as previously identified by our prior work[18]. We will adapt promotion, recruitment, delivery of the **'BETTER' prevention practitioner intervention** to the needs of residents of these clusters using

participatory research methods involving residents as well as stakeholders within the Durham Region, and we will also adapt the facilitation of **CDPS** actions to this scenario of deprivation.

3.0 *Primary objective and methods*

To detect an absolute increase of 30% or greater in the number of completed or ongoing CDPS actions, at an outcome assessment, six months after informed consent and baseline assessment of eligibility for each CDPS action, among participants in small areas randomized to be offered immediately the **'BETTER' prevention practitioner intervention**, compared to participants in wait-list control small areas (6 month waitlist prior to an outcome assessment and then being offered the 'BETTER' prevention practitioner intervention).

Participants in immediate intervention clusters and in wait-list clusters alike will receive standard printed material about chronic disease prevention and screening, as routinely available at the Durham Region Health Department (DRHD), following completion of a baseline survey interview administered to all participants who have given informed consent.

3.1 *Study design: **BETTER HEALTH: DURHAM***

We have planned a cluster randomized trial of the timing of the BETTER prevention practitioner intervention in order to test its effectiveness in the community setting of low income clusters, as opposed to the highly favourable Family Health Team practices which participated in the original BETTER study by Grunfeld et al[22]. The clusters are comprised of eligible low income census dissemination areas, or groups of eligible low income census dissemination areas. A total of 10 clusters will be randomly selected from a sampling frame of eligible clusters and 5 will be randomly assigned to be offered immediate prevention practitioner intervention and 5 will be randomly assigned six-month wait-list control (six month wait-list prior to prevention practitioner intervention). Study activity among the randomly selected and assigned clusters will be temporally staggered in order to maximize the efficiency of the research assistant prevention practitioner nurses.

" Pilot study: Prior to commencement of the study among the 10 randomly selected and assigned clusters, we will conduct a pilot study involving 6 consenting participants in each of two eligible clusters (one of which will be a six-month wait-list cluster) in order to assess the feasibility, appropriateness and suitability of promotion, recruitment, consent forms, and data collection instruments prior to the formal commencement of recruitment for the definitive study. "

Table 2 Timeline for intervention clusters and control clusters

Month >>	1	2	3	4	5	6	7	8	9
Intervention Clusters	Promotion, recruitment, informed consent, Intervention,			*CDPS activities for 6 months after* Intervention			Outcome measure		

	facilitation		
Control Clusters	Promotion, recruitment, informed consent, Standard information	*CDPS activities for 6 months after INFORMED CONSENT*	Outcome measure and offer intervention, facilitation*

* the outcome assessment is at 6 months post informed consent. For those participants in wait-list control clusters there will NOT be a second formal outcome assessment 6 months after the prevention practitioner intervention (i.e. no second formal outcome assessment 12 months post informed consent among 6 month 'wait-list delay' clusters).

From day 1 in each cluster, there will be three months of recruitment, informed consent, assessment, and in the case of intervention clusters, the prevention practitioner intervention. Each participant then will have 6 months to participate in **CDPS** actions prior to outcome assessment. Recruitment will be initiated in additional clusters approximately every three months. The rationale for control being a six-month 'wait-list' control is scientific and ethical: the challenges and barriers for **CDPS** actions are so great in the eligible low income clusters that a quantitative unbiased outcome comparison is required in order to study effectiveness of the prevention practitioner intervention in this context, in order to assess the scalability of this intervention outside of medical practices in communities with impaired access to primary care. We will compare participants living in immediate prevention practitioner intervention clusters to six-month wait-list control clusters, in order to obtain an unbiased estimate of the effect of prevention practitioners in low income clusters. On the other hand, it is unethical to request participants in control clusters to participate in outcome assessments but fail to provide them the opportunity to receive the **prevention practitioner** intervention, so those participants will be offered this intervention 6 months later, although the outcome of the delayed intervention is not a study outcome and will not be formally assessed or analyzed.

3.2 **'BETTER HEALTH: DURHAM'***: **Study population and sampling frame of clusters for randomization***

The sampling frame of clusters consists of low census dissemination areas (in Durham Region), where the lowest quintile of median household income and low cancer screening rates coincide. Low income clusters with low cancer screening rates have been identified by previous work[18].

The eligible population for recruitment in these clusters is men and women 40 - 64 years of age. Eligibility includes: homeless persons encountered in the low income clusters, persons already affected by one of the target cancers, diabetes, and / or circulatory diseases, persons up to date with any screening test, already engaged in some risk-reducing behaviours, or already meeting any risk-reducing targets at baseline assessment, illiterate English-speaking persons. Strategies to maintain communication with persons who are homeless or have difficult reading will be developed in each **cluster**. Exclusions: **non-English speakers**. **Only one person per household may participate in the study. Recruitment of men will be a challenge as only 30% of the participants in the original BETTER randomized trial were men.**

" We will purposively sample two eligible clusters from the sampling frame for the pilot study. These two clusters will then be removed from the sampling frame. "

3.3 **BETTER HEALTH: DURHAM***: Random assignment of clusters to immediate prevention practitioner intervention versus 6-month wait-list control prior to intervention)*

We will randomly sample low income clusters from the sampling frame in Durham Region, using the "sample( )" function contained in the statistical software package 'R'. A random number generator in R will then be used to randomly allocate clusters to the immediate intervention or to the wait-list control (the 6 month delayed intervention). The allocation process will be concealed from investigators.

3.4 **'BETTER'** *Intervention - Sample size calculation for effect size and adjusting for clustered exposure*

With an equal number of participants in 5 intervention clusters and 5 wait-list control clusters (the average number of eligible residents per cluster being 342), a total sample of 120 participants (on average 12 participants per cluster) will be required to detect an increase of 30% or greater in the composite index score (reflecting additional **CDPS** actions met among the intervention clusters (compared to the control clusters). The calculation is based on a two-sample comparison of means with 80% power and a 0.05 alpha. The calculation accounts for the design effect (correction factor determined as (1+(m-1)*rho)) arising from the clustered design, and an intracluster correlation coefficient (ICC) of rho = 0.237[22]. The ICC is a measure of the relatedness of the clustered data.

3.5 **BETTER HEALTH: DURHAM** *Promotion and recruitment*

Small area / community based strategies for promotion and recruitment[1,7,15,16,17,25,52] will be constructed using participatory research methods (see below, secondary objectives) to design cluster specific strategies with published evidence of effectiveness([1,7,15,16,17,25,52]). Online methods of recruitment, assessment and facilitation might exclude the majority of our target population[44]. Members of our team have been successful in community based recruitment[33,37]. Staff members at the DRHD know these clusters well, are experienced in health promotion campaigns among them, and are vital in the design and implementation of this strategy.

3.6 **BETTER HEALTH: DURHAM** *Informed consent and research ethics*

This research will be compliant with the Tri-Council Policy Statement on research ethics and the Ontario Personal Health Information Protection Act (2004).

We consider that the study population should be considered vulnerable from the point of view of economic deprivation and impaired access to primary care and will ensure to incorporate principles From the TCPS on the three core principles of Respect for Persons, Concern for Welfare, and Justice in all aspects of contact with potential and consenting participants in BETTER HEALTH: DURHAM

"Respect for Persons recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompassess the treatment of persons involved in research directly as participants....Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy."

"Autonomy includes the ability to deliberate about a decision and to act based on that deliberation. Respecting autonomy means giving due deference to a person's judgment and ensuring that the person is free to choose without interference. Autonomy is not exercised in isolation but is influenced by a person's various connections to family, to community, and to cultural, social, linguistic, religious and other groups. Likewise, a person's decisions can have an impact on any of these connections."

"Concern for Welfare: The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental, and spiritual health, as well as their physical, economic, and social circumstances. Thus, determinants of welfare can include housing, employment, security, family life, community membership, and social participation, among other aspects of life. Other contributing factors to welfare are privacy and the control of information about the person....according to the free, informed and ongoing consent of the person who was the source of the information or materials. A person's or group's welfare is also affected by the welfare of those who are important to them..."

"Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms or research, or denied the benefits of the knowledge generated from it. Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. One important difference that must be considered for fairneess and equity is vulnerability. Vulnerability is often caused by limited decision-making capacity, or limited access to social goods, such as rights, opportunities and power. .... People or groups whose circumstances cause them to be vulnerable or marginalized may need to be afforded special attention in order to be treated justly in research."

From the TCPS on Respect for Persons and consent:

"Respect for persons implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible. Where a person has the capacity to understand this information, and the ability to act on it voluntarily, the decision to participate is generally seen as an expression of autonomy. The Policy refers to the process of seeking consent from prospective participants, which may result in either agreement or refusal to participate. This process is meant to emphasize Respect for Persons. Under no circumstances may researchers proceed to conduct research with anyone who has refused to participate."

For participants in eligible and randomly selected and allocated low income clusters Informed consent will be requested for (1) collection of personal health information and personal contact information, and (2) for repeat contact at 6 months for outcome assessment. The study research assistant will obtain informed consent. Informed consent will also be obtained from all participants in key informant interviews and focus groups conducted in the course of the application of participatory research methods and integrated knowledge translation.

The study population living in the low income clusters is a vulnerable population. All study staff who will have contact with members of the study population will receive additional orientation to respectful relationships with this vulnerable population.

3.7 **BETTER HEALTH: DURHAM** *Baseline Data collection*

An entry survey will be administered as an interview by a research assistant, rather than self-administered as in the original BETTER study, because of literacy issues. Previous participation in, and eligibility for, CDPS actions will be determined by self-report. This will be administered in a variety of settings: for example, community centres and other safe venues identified by the participatory research methods in the low income clusters and environs. Data will be entered electronically with privacy / confidentiality, backup and data transfer conditions compliant with the requirements of the Office of the Privacy Commissioner of Ontario and the Research Ethics Board of Sunnybrook Health Sciences Centre. Data will be securely entered electronically directly to a database application created for BETTER HEALTH: DURHAM on a secure server the Applied Health Research Centre, St Michael's Hospital, Toronto (AHRC), access to which will be severely limited to the prevention practitioner nurses and to staff at AHRC involved in the maintenance and analysis of the study data (see Appendix 9).

3.8 **BETTER HEALTH: DURHAM** *Prevention Practitioners*

Prevention Practitioners will be public health nurses employed by the DRHD, who have had intensive training in administration of 'BETTER' using effective educational methods [1,7,15,16,17,25,42,52] . These methods include interviewing with shared decision making, brief action plans, in the context of small group discussions and role-playing. [(22,42)]

The process of interviewing and goal setting was described in the publication of the 'BETTER' trial: "Through motivational interviewing and shared decision-making, a personalized 'prevention prescription' was prepared by the Prevention Practitioner during the visit. This prescription was tailored to that patient's chronic disease risk, which also included their family history. The prevention prescription focused on optimum use of existing capacity, tools and community resources that were available. "[22] See Appendix 5 for summary of concepts underlying the meeting, and visual aids.

We will request informed consent from up to 50 participants in immediate intervention clusters for audiotaping of the meeting with the prevention practitioner nurse, for purposes of quality assurance

assessment of the prevention practitioner nurse's conduct of the meeting, adapting the methods of Miller[62] and of Moyer[63].

Prevention practitioners will participate in the participatory research methods and facilitation of CDPS. We have allocated an average of 4 hours of public health nurse / prevention practitioner time per each of 352 participants; including an average of 3 hours for direct participant contact and follow-up and 1 hour for other study activities (meetings etc.)

The prevention practitioner nurses will enter a limited amount of self-reported data from participants about goals and self-referrals, using the same secure method described above in 3.7 for the self-report data collected by the research assistant.

3.9. **'BETTER HEALTH: DURHAM***: Social determinants of health*

Social determinants of health are very powerful predictors of health status and health behaviour across the socio-economic spectrum. Demographic and socio-economic factors will be collected at the baseline survey interview and 6 month outcome survey interview for exploratory analyses of their relationship to the accomplishment of **CDPS** activities. Such information is highly sensitive as any personal health information and will be handled with the same privacy and confidentiality procedures as described in 3.7.

Should participants request information from prevention practitioner nurses about how to self-refer to agencies that address social determinants of health such as housing, income support, or family services, the frequency of such requests will also be computed, having treated such a request for information on how to self-refer with the same privacy and confidentiality procedures as described in 3.7.

3.10 **BETTER HEALTH: DURHAM** *Facilitation of **CDPS** goals*

Facilitation of the achievement of **CPDS** goals and targets in the prevention prescription in the first 'BETTER' trial was by a combination of prevention practitioner activity as well as by Family Health Team staff, and self-direction[22]. In this study, participants may lack a primary care physician (PCP), at least initially, and may face other barriers such as limited access to online information, and have limited access to transportation, and limited financial resources, compared to the average participant in previous **'BETTER'** studies. The prevention practitioner nurses will have information available to to provide to participants who do not have a primary care provider about primary care physicians and nurse practitioners nearby who have stated their willingness to accept additional new patients. Facilitation will include identification of appropriate services and activities for individual participants according to their personally chosen **CDPS** actions and finding strategies to overcome particular barriers encountered by individual participants.

Participants with a primary care physician *will have any screening tests and their follow-up done by that PCP.*

Blood pressure, weight, and waist circumference measures will be performed by the prevention practitioner.

Among participants without a primary care physician blood draws and distribution of stool testing kits will be done by nurse practitioner requisition. We have allocated on average one hour of nurse practitioner time per participant. For women desiring to have a pap smear and who do not have a physician to do this, appropriate arrangements will be made by the nurse practitioner. Nurse practitioners in Ontario are now authorized to make referrals to specialist physicians based on abnormal results received from investigations ordered by the nurse practitioners. However, as a fail-safe, several members of the investigative team are also primary care physicians would be available on a rotating basis to deal with situations in which the nurse practitioner has been unable to make a necessary referral for abnormal screening results.

3.11 **BETTER HEALTH*: DURHAM*** *Assistance to find PCP*

Prior to the commencement of recruitment, the study investigators, in concert with all those stakeholders involved in the participatory research methods, will have identified nurse practitioners and primary care physicians who have agreed to accept new patients for those participants who do not have a primary care provider and who wish to have one. *The participatory research methods for this project will include a primary care strategy to engage primary care providers in the adaptation of the intervention and in the identification of primary care providers who would be willing to accept as new patients participants who do not have one.*

3.12 **BETTER HEALTH: DURHAM** *Followup of normal and abnormal results of screening tests among participants who still do not have a primary care provider.*

Normal results will be disclosed to the participant by the research assistant.

Abnormal results will be disclosed to the participant by the nurse practitioner.

In the case of critical results from specimen examinations for which the nurse practitioner has been unable to obtain an appropriate medical consultation, the results will be reported immediately to one of the primary care investigators (according to a pre-determined roster of duty) for urgent action and / or for referral to specialist.

In the case of abnormal but less critical results requiring prompt referral (e.g. high grade cytology on PAP), for which the nurse practitioner has been unable to obtain an appropriate medical consultation the primary care investigators (Lofters, Pinto) will make the appropriate referral for any person for whom the prevention practitioner has been unable to link to a primary care physician.

3.13 **BETTER HEALTH: DURHAM***: Outcome ascertainment*

Six months after the baseline survey interview, the research assistant will administer the outcome survey on health and CDPS actions to participants in intervention and control clusters alike. All outcomes are self-reports of the completion of CDPS actions. The data will be securely entered directly to the database application on the secure server at AHRC as described above in 3.7. Results of any screening tests ordered by the nurse practitioner at the request of the participant are NOT part of the study data and will be retained securely only at the DRHD.

At the time of the six month outcome survey interview, the research assistant will offer each participant in wait-list control clusters the opportunity to receive the BETTER intervention with a prevention practitioner. Outcome data will NOT be collected for analysis six months after the delayed BETTER intervention in wait-list control clusters. See Appendix 2 for pathway and data collection.

3.14 **BETTER HEALTH: DURHAM** *Primary Outcome Measure*

The primary outcome measure is a composite index, expressed as the ratio (multiplied by 100) of the number of eligible **CDPS** actions at baseline (denominator) that are subsequently met (by self-report) at follow-up (numerator), measured at the patient level. The composite index is modeled after the **S**ummary **Qu**ality **I**n**d**ex (**SQUID**) introduced by Nietert for assessing the quality of primary care interventions[48]. As a function of baseline characteristics, certain individuals are 'eligible' for certain **CDPS** actions. At follow-up, each patient will be re-evaluated and the number of eligible actions … 'met' will be enumerated. For example, eligible actions would be smoking cessation in a smoking patient or a mammogram in a patient not up-to-date with mammograms. In this case, the actions would be designated 'met' if the patient had quit smoking and had a screening mammogram at follow-up. If the patient had not quite smoking or the mammogram was not completed at follow-up these actions were considered 'not met'. [22]

3.15 **BETTER HEALTH: DURHAM** *Secondary outcome measures related to primary objective*

We will report the frequency with which individual CDPS actions were completed. We will report the frequency with which self-referrals were reported to the prevention practitioner.

4.0 Secondary objectives and methods:

4.1 Secondary Objective 4.1. *To adapt, revise and tailor 'BETTER' to the needs of those in low income clusters, using community-based participatory research principles*

We will use community-based participatory research (CBPR) principles to guide the adaptation of 'BETTER'. CBPR is a "collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied…in all aspects of the research process to improve health and well-being through taking action including social change."[59]. A CBPR approach has improved the quality of interventions in a variety of community settings [26, 59]. Principles of CBPR are consistent with those of community engagement endorsed in Ontario. In particular, the Durham Region Health Department (DRHD) has adopted community engagement principles[38,49].

4.11 ***Specific Approach to Adapting BETTER*****:** The specific process of adaption of BETTER will follow the ADAPT-ITT steps [61] (Appendix 4a). Stakeholders including Prevention Practitioners, Nurse Practitioners, public health, primary care, and community stakeholders will be invited to a meeting to introduce elements of BETTER and overall study goals and approach. Subsequently, research team members will conduct small group meetings with members of the public who are potentially eligible for BETTER, and community stakeholders, to discuss specific needs, and the fit of BETTER to those needs. Extensive notes will be taken at the meetings and all suggestions will be documented. Adaptations of 'BETTER' will be made considering the needs of the community, balanced with BETTER fidelity to core elements, discussed in follow up meetings, and pilot-tested. PPs will receive extensive training in the adapted BETTER intervention. The adaptation and implementation of 'BETTER' will be evaluated using qualitative methods (see below).

4.2 Secondary Objective 4.2. ***To conduct a qualitative evaluation of the implementation of the adapted 'BETTER',*** considering perceived effectiveness, facilitators and barriers, and benefits and disadvantages, and sustainability in low income clusters and among those who have not had a PCP.

We have adapted the approach taken for the evaluation of 'BETTER' in Newfoundland and NWT[42]. The key questions to guide the qualitative evaluation are: 1. How was 'BETTER' adapted? 2. What has been the impact of 'BETTER' as perceived by stakeholders? 3. What barriers and enablers of 'BETTER' have been encountered? 4. What are the benefits and disadvantages of 'BETTER' '? , and 5) How can the implementation of 'BETTER' be sustained?

4.21 ***Specific Methods*****:** We will use a qualitative approach based on grounded theory[19] and informed by the Consolidated Framework for Implementation Research (CFIR) [14] (Appendix 4) to evaluate the adaptation and implementation of 'BETTER'. Grounded theory is a well-known qualitative method suited to examining a phenomenon, such as the adaptation and implementation of 'BETTER', within the context of offering BETTER through the DRHD in low income clusters[19]. CFIR was developed from existing implementation frameworks and illustrates interrelationships among five different domains[14]. Given the complexity of the adaptation and implementation processes for 'BETTER', all potentially relevant domains (the intervention, the inner and outer settings, individuals involved, and the process of implementation) will be considered. Constructs for each domain of CFIR have been described [14] which will facilitate interpretation during data coding and analytic processes (described below).

4.22 ***Data collection*****:** We will collect qualitative data three times during the project place: 1) at the beginning of the study to assist with adaptation and start-up issues (Year 1); 2) after the intervention is established to understand perceived enablers and barriers, benefits and disadvantages (Years 2-3), and 3) near the end of the study (Year 4) to explore sustainability and impact. Data collection strategies will include focus groups and one-to-one, semi-structured interviews with a range of participants: 1) members of the public eligible for BETTER who live in low income clusters that not be participating as well as clusters that will be participating; 2) prevention practitioners who are providing the BETTER intervention; 3) public health unit (PHU) Medical Officer of Health (MOH) and their staff; 4) primary care physicians; 5) nurse practitioners, and 6) other community stakeholders. Interview guides will be based on the study objectives and revised periodically to seek contrasting and supporting data. Interviews will

be recorded and transcribed verbatim and field notes will be created to document non-verbal and contextual information.

4.23 ***Recruitment of participants to participatory research methods****:*

Members of the public who are potentially eligible for BETTER (for adaptation component), will be nominated by the DRHD, community groups, or community health professionals and by prevention practitioners (during implementation phase). Stakeholders will be approached by the research team or by staff members of the DRHD. Potential participants will receive a detailed letter of information describing the study and inviting them to participate. Residents of low income clusters will be offered $25.00 in recognition of their time and their transportation costs (public transit or parking) will be reimbursed. Participants will provide informed consent. The number of interviews or focus groups depends on data saturation. Saturation occurs when data categories are dense and no new or relevant data are being [6].

Among residents of eligible low income clusters we estimate up to 20 key informant interviews and up to 5 focus groups of approximately 8 persons each. Among residents of low income clusters selected by the random process and therefore not clusters for recruitment of participants in the comparison of immediate intervention versus 6 month 'wait-list delay', we also estimate up to 20 key informant interviews and up to 5 focus groups of approximately 8 persons each.

Among stakeholders we estimate 25 key informant interviews and 10 focus groups of 8 persons each. Stakeholders will not be offered payment for their time because of limited funding available for this study.

4.3 Secondary Objective 4.3. To share the adapted BETTER knowledge products and study results with a wide range of stakeholders including policy makers and advisors, public health, primary care, community and national organizations, and with a larger research audience, using a KT framework.

4.31 ***Knowledge Translation Plan:*** Integrated and end-of-grant knowledge translation (KT) activities are central to the adaption and implementation of 'BETTER'. The CIHR Knowledge to Action process is one of our guiding frameworks. It has been adapted taking into consideration the needs of the project (Appendix 4. Adapted Knowledge to Action Process)

4.32 ***Integrated KT:*** Integrated KT will be ongoing throughout all phases of the study including adaptation of BETTER, implementation and evaluation. The CBPR approach in [14] this study will facilitate integrated KT. For example, staff members of the DRHD have been involved in the creation of this proposal. During adaptation of BETTER, we will consult with key stakeholders including members of the public who are eligible for **CDPS** activities in low income clusters, and leaders of community organizations who have insights of different facets of the adaptation and implementation process, and who will have a stake in the study results. If it proves difficult to engage members of the public in the project, we will follow the advice of community leaders who have in-depth knowledge of the low income clusters and the optimal methods to seek their participation. We anticipate that bidirectional communication will occur in one to one, small and large group interactive face-to-face meetings.

Ongoing project updates will be provided via Facebook, and websites. Early communication from stakeholders will shape subsequent messages, and avenues for integrated KT to meet needs. The effectiveness of integrated KT will be assessed as part of the qualitative evaluation. Early evaluation will uncover strengths and weaknesses of the integrated KT approach so that new strategies can be developed if needed.

4.33 ***End-of-Grant KT:*** We will hold a summative KT workshop at the end of the study involving all stakeholders. Multiple small group meetings will be held in Durham Region, to reach all stakeholders. Study briefing notes will be created and tailored to different stakeholder needs (determined using data from the qualitative evaluation). Abstracts for academic presentations and workshops will be submitted to the chronic disease prevention annual conference. Manuscripts will be submitted to Implementation Science, BMC Public Health, BMC Family Practice, the Journal of Medical Screening, and CMAJOpen.

5.0 ANALYSIS PLANS:

5.1 ***Primary Objective*** Analysis of the primary outcome (absolute percent increase in eligible **CDPS** actions completed or engaged in) will account for the correlation among outcomes which may arise from individuals within the same cluster. This will be done by implementing a two-level hierarchical regression model[15]. Specifically, a generalized linear random effects regression model will be constructed in which a cluster-specific random effect, arising from a normal distribution, will be included to account for the dependency among outcomes of individuals within the same cluster[46,47,58]. The main binary exposure in the hierarchical model will be immediate 'BETTER' compared to 'wait-list' control; furthermore any characteristics that were not balanced (between the immediate 'BETTER' and 'wait-list controls') from the randomization process will be adjusted for in the hierarchical regression model. In addition to obtaining estimates of the regression parameters, the hierarchical regression model will allow us to investigate the percent of residual or unexplained variation attributable to each level of the hierarchy. Hierarchical regression analyses will be conducted using the statistical programming package MLWIN (Centre for Multilevel Modeling, Bristol, UK). See Appendix 3 for quantitative analysis plan.

5.2 ***Secondary objectives*** We will use the constant comparative method for data analysis[4,19]. Initially, two team members will code approximately 2-3 transcripts in each data collection phases using an editing style of coding[13]. From the codes identified during this process, a preliminary coding guide will be developed and reviewed with all team members. Subsequently, a research assistant will code the remaining transcripts using the coding guide. We will hold periodic analysis meetings with several team members to review the codes, sort codes into categories and identify main themes[4,19]. Team members will create memos that will document emerging relationships among the codes and categories. We will use data management and analysis software (NVivo 10, QSR International). An audit trail including interview summaries and memos will be used to document all major decisions[24].

5.21 *Rigor of Qualitative Methods.* Involvement of several members of the research team during the analytic process will ensure that identified themes are consistent with coded data. We will use data triangulation in which data from several sources are examined to provide a full description of the

themes. As noted above, the use of the audit trail will ensure transparency of major decisions that are made during data collection and analysis.

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Appendix 1: Comparison of the original BETTER study in primary care[22], and this project

	BETTER *in primary care practices*	BETTER HEALTH: DURHAM
Physical location of prevention practitioner (PP)	In primary care team clinics	Imbedded in Health Department, Durham Region, for community outreach
Identification of participants	From electronic medical record	Community-based recruitment strategies in low income clusters
Informed consent	For collection of personal health information, by prevention practitioner	For collection of self-reported personal health information, by research assistant
Identification of completed and current behaviours and activities	From electronic medical record, and from self-report in self-administered survey	From self-report responses to survey administered by research assistant
Data collection	Paper	Electronic
Identification of risk factors	Lab tests , survey, electronic medical record	Self report
Brief action plan interview by PP and goal-setting by participants	By prevention practitioner in primary care team clinics	By prevention practitioners at various community locations
Height, weight, waist circumference, blood pressure	EMR PP / PCP	Prevention practitioner
Specimen collection for laboratory-based screening	In primary care clinics	Various locations, by nurse practitioners for those without MD
Facilitation of goal achievement	**Clinic staff**, prevention practitioner, links, and self	Prevention practitioners, links, and self
Strategy to find primary care physician for participants.	Not applicable	Prevention practitioners supported by primary care strategy engaging physicians and clinics near the clusters.
Followup of abnormal results	By primary care physician	By prevention practitioner, nurse practitioner, primary care physicians, with back up by primary care physician-investigators in the event of results requiring urgent action for those without primary care physicians.
Primary outcome measures	"composite index, expressed as the ratio (multiplied by 100) of the number of eligible CDPS (chronic disease prevention and screening) actions at baseline (denominator) that were subsequently met at follow-up (numerator), measured at the patient level."(G*)	
Ascertainment of outcomes	Abstraction from EMR and self-report responses at repeat self-administered survey by prevention practitioner	Biometrics collected by prevention practitioner and self-report responses to survey administered by research assistant

Appendix 2: BETTER HEALTH: DURHAM Pathway of participants and their quantitative data

Community based promotion and recruitment

Potential participant gives *name, sex, age, address and phone number to research assistant*

Research assistant (1) determines if potential participant is eligible by age and address, (2) notifies potential participant and (3) offers to meet to explain study and explain informed consent form.

Potential participant meets research assistant to consider whether to participate and whether to consent or not

If decides to consent, Study ID assigned to participant by research assistant and research assistant determines cluster identifier.

Study ID linked to name, address and phone number in confidential secure file at the Durham Region Health Department (DRHD)

Informed consent form kept in confidential secure file at the DRHD.

If decides to withhold consent, name, address, and phone number deleted; sex and age retained for statistics on refusals to consent.

version Jan 30, 2017

Consenting participant completes baseline survey via interview with research assistant.

Responses entered electronically by research assistant securely and directly online into database on secure server at Applied Health Research Centre, St Michael's Hospital (AHRC) ; responses identified only by study ID, age, sex, cluster identifier (letter code), and cluster category (immediate intervention versus wait-list control) .

Eligible Chronic Disease Prevention and Screening activities and prevention prescription are electronically computed for future use by prevention practitioner nurse and for final analysis.

In preparation for, and during, meeting with prevention practitioner nurse, the prevention practitioner nurse securely accesses the data directly on the secure server at AHRC.

Participants living in immediate intervention clusters:

If participant lives in an immediate intervention cluster, prevention practitioner nurse contacts participant to set up appointment for brief action planning / shared decision making.

Prevention practitioner nurse refers to information remotely and securely via computer, and follows prompts from computer as well as interests and wishes of participant.

Participant and prevention practitioner nurse work together to create prevention prescription and goals for chronic disease prevention and screening activities.

Prevention practitioner nurse enters biometrics (for calculation of BMI and achievement of certain CDPS actions), individual goals, and referrals for prevention prescription directly and securely into the database application on the server at AHRC.

Participant receives paper document of prevention prescription and goals.

Prevention practitioner nurse facilitates goal setting and completion of Chronic Disease Prevention and Screening Activities.

Electronic prompt to research assistant to contact participant in order to schedule 6 month outcome survey.

Research assistant contacts participant 6 month's later to conduct outcome survey and enters responses securely and remotely into database application on secure server at AHRC.

OR

Participants living in wait-list control clusters:

Electronic prompt to research assistant to contact participant in order to schedule 6 month outcome survey.

If participant lives in wait - list control cluster, research assistant contacts participant 6 months later to conduct outcome survey and enters responses electronically into tablet computer.

Prevention practitioner nurse contacts participant to set up appointment for brief action planning / shared decision-making.

Prevention practitioner nurse refers to information securely and remotely by computer and follows prompts from computer as well as interests and wishes of participant.

Participant and prevention practitioner nurse work together to create prevention prescription and goals for chronic disease prevention and screening activities.

Participant receives paper document of prevention prescription and goals.

Prevention practitioner nurse enters biometrics (for calculation of BMI and achievement of certain CDPS actions), individual goals, and referrals for prevention prescription.

Prevention practitioner nurse facilitates goal setting and completion of Chronic Disease Prevention and Screening Activities.

Appendix 3:

BETTER HEALTH: DURHAM Quantitative analysis plan

Consort table

Number of self-referrals for potential participation **N =**

Number assessed for eligibility (age 40 - 64, residence in eligible cluster, no other member of household already participating) **N =**

Number to whom the study is offered **N =**

Number offered who consent **N =**

Those who consent and who reside in immediate intervention clusters

Number who consent who complete baseline survey **N =**

Number who complete baseline survey in immediate intervention clusters who attend prevention practitioner interview **N =**

Number in immediate intervention clusters who complete six month outcome survey after prevention practitioner interview **N =**

Those who consent and who reside in wait-list control clusters

Number who consent who complete baseline survey **N =**

Number in wait-list control clusters who complete six month outcome survey **N =**

Number in wait-list control clusters who attend prevention practitioner interview after six month outcome survey **N =**

Table 1a Baseline characteristics of participants by cluster

	Immediate intervention clusters	Wait-list control clusters	Overall
Age mean, SD median, IQR			
Sex male female	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
Minority race or ethnic group Yes No	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
Education >= 1 year post secondary education yes no	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
Marital status Married / common law Other	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
Income >= 60,000 CAD < 60,000 CAD	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
Current smoker Yes No	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
Current alcohol consumption < 4 times per month >= 2 times per week other	 n, cell % n, cell % n, cell %	 n, cell % n, cell % n, cell %	 n, cell % n, cell % n, cell %
Exercise status <= mildly active Other	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
BMI mean, SD median, IQR			
Obesity yes No	 n, cell % n, cell %	 n, cell % n, cell %	 n, cell % n, cell %
MOS social support score* mean, SD median, IQR			
Followup time (days)			

mean, SD median, IQR			

*MOS social support scale is included in Baseline Survey Interview

Table 1b Additional description of study population

	Immediate intervention clusters	Wait-list control clusters	Overall
Age			
40 - 44	n, cell %	n, cell %	n, cell %
45 - 49	n, cell %	n, cell %	n, cell %
50 - 54	n, cell %	n, cell %	n, cell %
55 - 59	n, cell %	n, cell %	n, cell %
60 - 64	n, cell %	n, cell %	n, cell %
Caucasian / white	n, cell %	n, cell %	n, cell %
Southeast Asian	n, cell %	n, cell %	n, cell %
East Asian	n, cell %	n, cell %	n, cell %
South Asian	n, cell %	n, cell %	n, cell %
Black	n, cell %	n, cell %	n, cell %
Aboriginal	n, cell %	n, cell %	n, cell %
-first nations	n, cell %	n, cell %	n, cell %
-metis	n, cell %	n, cell %	n, cell %
-inuit	n, cell %	n, cell %	n, cell %
Other:	n, cell %	n, cell %	n, cell %
Education			
Elementary school or less	n, cell %	n, cell %	n, cell %
Some high school	n, cell %	n, cell %	n, cell %
Completed high school	n, cell %	n, cell %	n, cell %
Some college or technical school	n, cell %	n, cell %	n, cell %
Completed college or technical school	n, cell %	n, cell %	n, cell %
Some university	n, cell %	n, cell %	n, cell %
Completed bachelor's degree	n, cell %	n, cell %	n, cell %
Graduate or professional degree	n, cell %	n, cell %	n, cell %

	Immediate intervention clusters	Wait-list control clusters	Overall
Employment status			
>= 30 hours per week	n, cell %	n, cell %	n, cell %
>0 < 30 hours per week	n, cell %	n, cell %	n, cell %
unable to work because of sickness or disability	n, cell %	n, cell %	n, cell %
looking after home and / or family	n, cell %	n, cell %	n, cell %
Student	n, cell %	n, cell %	n, cell %
retired	n, cell %	n, cell %	n, cell %
unemployed	n, cell %	n, cell %	n, cell %
Marital status			
Married / common law	n, cell %	n, cell %	n, cell %
Other	n, cell %	n, cell %	n, cell %
Number of persons in household (including self)			
mean, SD			
median, IQR			
Household income before taxes from all sources			
< 10,000	n, cell %	n, cell %	n, cell %
10,000 - 19,999	n, cell %	n, cell %	n, cell %
20,000 - 39,999	n, cell %	n, cell %	n, cell %
40,000 - 59,999	n, cell %	n, cell %	n, cell %
>= 60,000	n, cell %	n, cell %	n, cell %
History of diabetes			
Yes	n, cell %	n, cell %	n, cell %
No	n, cell %	n, cell %	n, cell %
History of hypertension			
Yes	n, cell %	n, cell %	n, cell %
No	n, cell %	n, cell %	n, cell %
History of stroke			
Yes	n, cell %	n, cell %	n, cell %
No	n, cell %	n, cell %	n, cell %
History of coronary heart disease			
Yes	n, cell %	n, cell %	n, cell %
No	n, cell %	n, cell %	n, cell %

Table 1c Baseline lifestyle and nutrition items

	Immediate intervention clusters	Wait-list control clusters	Overall
EXERCISE			
Exercise >= once weekly			
Yes	n, cell %	n, cell %	n, cell %
No	n, cell %	n, cell %	n, cell %
Minutes spent excercising weekly			
mean, SD			
median , IQR			
Physical activity involved in work			
-not employed	n, cell %	n, cell %	n, cell %
-mostly sitting	n, cell %	n, cell %	n, cell %
-mostly standing or walking	n, cell %	n, cell %	n, cell %
-definite physical effort	n, cell %	n, cell %	n, cell %
-vigorous physical activity	n, cell %	n, cell %	n, cell %
Usual walking pace			
-slow pace	n, cell %	n, cell %	n, cell %
-steady average pace	n, cell %	n, cell %	n, cell %
-brisk pace	n, cell %	n, cell %	n, cell %
-fast pace	n, cell %	n, cell %	n, cell %
NUTRITION			
Fast food and snacks per week			
0	n, cell %	n, cell %	n, cell %
1 - 3 times	n, cell %	n, cell %	n, cell %
>= 4 times	n, cell %	n, cell %	n, cell %
Servings of fruit per day			
<= 2	n, cell %	n, cell %	n, cell %
3 - 4	n, cell %	n, cell %	n, cell %
>= 5	n, cell %	n, cell %	n, cell %
Servings of vegetables per day			
<= 2	n, cell %	n, cell %	n, cell %
3 - 4	n, cell %	n, cell %	n, cell %
>= 5	n, cell %	n, cell %	n, cell %
Sweetened beverages per day			
0	n, cell %	n, cell %	n, cell %
1 - 2	n, cell %	n, cell %	n, cell %
>= 3	n, cell %	n, cell %	n, cell %
Snack chips or crackers per week			
<= 1	n, cell %	n, cell %	n, cell %
2 - 3	n, cell %	n, cell %	n, cell %
>= 4	n, cell %	n, cell %	n, cell %

Desserts and other sweets per week			
<= 1	n, cell %	n, cell %	n, cell %
2 - 3	n, cell %	n, cell %	n, cell %
>= 4	n, cell %	n, cell %	n, cell %
ALCOHOL			
Drinks containing alcohol			
-never	n, cell %	n, cell %	n, cell %
-monthly or less	n, cell %	n, cell %	n, cell %
-2 - 4 times per month	n, cell %	n, cell %	n, cell %
-2 - 3 times per week	n, cell %	n, cell %	n, cell %
->= 4 times per week	n, cell %	n, cell %	n, cell %
How often do you have >= 6 drinks on one occasion?			
-never	n, cell %	n, cell %	n, cell %
-less than monthly	n, cell %	n, cell %	n, cell %
-monthly	n, cell %	n, cell %	n, cell %
-weekly	n, cell %	n, cell %	n, cell %
-daily or almost daily	n, cell %	n, cell %	n, cell %

Table 2 Baseline eligibility of participants for chronic disease prevention and screening (CDPS) actions by randomization cluster (count and %)

Original SQUID ID number	Action descriptor	Immediate intervention clusters	Wait-list control clusters	Overall
1	fasting blood sugar or HgB A1C screen	n, cell %	n, cell %	n, cell %
3	Blood pressure screen	n, cell %	n, cell %	n, cell %
4	Blood pressure monitor	n, cell %	n, cell %	n, cell %
6	Measurement of low density lipoproteins	n, cell %	n, cell %	n, cell %
10	Screening mammography	n, cell %	n, cell %	n, cell %
11	Colorectal screening	n, cell %	n, cell %	n, cell %
12	Cervical screening / pap smear	n, cell %	n, cell %	n, cell %
13	BMI screening	n, cell %	n, cell %	n, cell %
14	Waist circumference measurement	n, cell %	n, cell %	n, cell %
15	Weight control	n, cell %	n, cell %	n, cell %
16	Referral for BMI > 25	n, cell %	n, cell %	n, cell %
18	Smoking cessation	n, cell %	n, cell %	n, cell %
19	Smoking cessation referral	n, cell %	n, cell %	n, cell %
21	Alcohol control	n, cell %	n, cell %	n, cell %
22	Alcohol control referral	n, cell %	n, cell %	n, cell %
24	Physical activity >= 90 minutes	n, cell %	n, cell %	n, cell %
25	Physical activity referral	n, cell %	n, cell %	n, cell %
27	Healthy diet score	n, cell %	n, cell %	n, cell %
28	Nutrition referral	n, cell %	n, cell %	n, cell %

Table 3 Percent of eligibles, by cluster, who complete eligible CDPS actions

Original SQUID ID number	Action descriptor	Immediate intervention clusters	Wait-list control clusters	Overall
1	fasting blood sugar or HgB A1C screen	n, cell %	n, cell %	n, cell %
3	Blood pressure screen	n, cell %	n, cell %	n, cell %
4	Blood pressure monitor	n, cell %	n, cell %	n, cell %
6	Measurement of low density lipoproteins	n, cell %	n, cell %	n, cell %
10	Screening mammography	n, cell %	n, cell %	n, cell %
11	Colorectal screening	n, cell %	n, cell %	n, cell %
12	Cervical screening / pap smear	n, cell %	n, cell %	n, cell %
13	BMI screening	n, cell %	n, cell %	n, cell %
14	Waist circumference measurement	n, cell %	n, cell %	n, cell %
15	Weight control	n, cell %	n, cell %	n, cell %
16	Referral for BMI > 25	n, cell %	n, cell %	n, cell %
18	Smoking cessation	n, cell %	n, cell %	n, cell %
19	Smoking cessation referral	n, cell %	n, cell %	n, cell %
21	Alcohol control	n, cell %	n, cell %	n, cell %
22	Alcohol control referral	n, cell %	n, cell %	n, cell %
24	Physical activity >= 90 minutes	n, cell %	n, cell %	n, cell %
25	Physical activity referral	n, cell %	n, cell %	n, cell %
27	Healthy diet score	n, cell %	n, cell %	n, cell %
28	Nutrition referral	n, cell %	n, cell %	n, cell %

Table 4: Percent of eligibles who complete CHOSEN SQUID actions (set as goals by participant) (cell denominators will be smaller than for Table 4: not all eligible, but all eligible who set action as a goal)

Original SQUID ID number	Action descriptor	Immediate intervention clusters	Wait-list control clusters	Overall
1	fasting blood sugar or HgB A1C screen	n, cell %	n, cell %	n, cell %
3	Blood pressure screen	n, cell %	n, cell %	n, cell %
4	Blood pressure monitor	n, cell %	n, cell %	n, cell %
6	Measurement of low density lipoproteins	n, cell %	n, cell %	n, cell %
10	Screening mammography	n, cell %	n, cell %	n, cell %
11	Colorectal screening	n, cell %	n, cell %	n, cell %
12	Cervical screening / pap smear	n, cell %	n, cell %	n, cell %
13	BMI screening	n, cell %	n, cell %	n, cell %
14	Waist circumference measurement	n, cell %	n, cell %	n, cell %
15	Weight control	n, cell %	n, cell %	n, cell %
16	Referral for BMI > 25	n, cell %	n, cell %	n, cell %
18	Smoking cessation	n, cell %	n, cell %	n, cell %
19	Smoking cessation referral	n, cell %	n, cell %	n, cell %
21	Alcohol control	n, cell %	n, cell %	n, cell %
22	Alcohol control referral	n, cell %	n, cell %	n, cell %
24	Physical activity >= 90 minutes	n, cell %	n, cell %	n, cell %
25	Physical activity referral	n, cell %	n, cell %	n, cell %
27	Healthy diet score	n, cell %	n, cell %	n, cell %
28	Nutrition referral	n, cell %	n, cell %	n, cell %

Table 5: CDPS and SQUID by randomization group overall and by age stratum and by sex stratum

	Immediate intervention clusters	Wait-list control clusters	Overall
OVERALL			
Number of eligible CDPS actions mean, SD median, IQR			
Number of eligible CDPS actions completed mean, SD median, IQR			
Unadjusted SQUID			
Adjusted SQUID			
Age stratum 40 - 49			
Number of eligible CDPS actions mean, SD median, IQR			
Number of eligible CDPS actions completed mean, SD median, IQR			
Unadjusted SQUID			
Adjusted SQUID			

	Immediate intervention clusters	Wait-list control clusters	Overall
Age stratum, 50 - 64			
Number of eligible CDPS actions mean, SD median, IQR			
Number of eligible CDPS actions completed mean, SD median, IQR			
Unadjusted SQUID			
Adjusted SQUID			
Females			
Number of eligible CDPS actions mean, SD median, IQR			
Number of eligible CDPS actions completed mean, SD median, IQR			
Unadjusted SQUID			
Adjusted SQUID			
Males			
Number of eligible CDPS actions mean, SD median, IQR			
Number of eligible CDPS actions completed mean, SD median, IQR			
Unadjusted SQUID			
Adjusted SQUID			

Computation of unadjusted and adjusted SQUID

The primary outcome measure is a composite index, expressed as the ratio (multiplied by 100) of the number of eligible **CDPS** actions at baseline (denominator) that are subsequently met at follow-up (numerator), measured at the patient level. The composite index is modeled after the **S**ummary **Qu**ality **I**n**d**ex (**SQUID**) introduced by Nietert for assessing the quality of primary care interventions[48]. As a function of baseline characteristics, certain individuals are 'eligible' for certain **CDPS** actions. At follow-up, each patient will be re-evaluated and the number of eligible actions … 'met' will be enumerated. For example, eligible actions would be smoking cessation in a smoking patient or a mammogram in a patient not up-to-date with mammograms. In this case, the actions would be designated 'met' if the patient had quit smoking and had a screening mammogram at follow-up. If the patient had not quite smoking or the mammogram was not completed at follow-up these actions were considered 'not met'. [22]

22. Grunfeld E, Manca D, Moineddin R, Thorpe KE, Hoch JS, Campbell-Scherer D, Meaney C, Rogers J, Beca J, Krueger P, Mamdani M for the BETTER Trial Investigators
Improving chronic disease prevention and screening in primary care: results of the BETTER pragmatic cluster randomized controlled trial.
BMC Family Practice 2013, 14: 175.

48. Nietert PJ, Wessell AM, Jenkins RG, et al:
Using a summary measure for multiple quality indicators in primary care: the summary QUality InDex (SQUID).
Implementation Sci 2007, 2:11.

Analysis of the primary outcome (absolute percent increase in eligible **CDPS** actions completed or engaged in) will account for the correlation among outcomes which may arise from individuals within the same cluster. This will be done by implementing a two-level hierarchical regression model[56]. Specifically, a generalized linear random effects regression model will be constructed in which a cluster-specific random effect, arising from a normal distribution, will be included to account for the dependency among outcomes of individuals within the same cluster[46,47,58]. The main binary exposure in the hierarchical model will be immediate 'BETTER' compared to 'wait-list' control; furthermore any characteristics that were not balanced (between the immediate 'BETTER' and 'wait-list controls') from the randomization process will be adjusted for in the hierarchical regression model. In addition to obtaining estimates of the regression parameters, the hierarchical regression model will allow us to investigate the percent of residual or unexplained variation attributable to each level of the hierarchy. Hierarchical regression analyses will be conducted using the statistical programming package MLWIN (Centre for Multilevel Modeling, Bristol, UK).

46. Murray DM, Rooney BL, Hannan PJ, et al.
Intraclass correlation among common measures of adolescent smoking.
Am J Epidemiol. 1992;140:1038-1050.

47. Murray, D. M. (1998).
Design and analysis of group-randomized trials.

Oxford: Oxford University Press.

48. Nietert PJ, Wessell AM, Jenkins RG, et al:
Using a summary measure for multiple quality indicators in primary care: the summary QUality InDex (SQUID).
Implementation Sci 2007, 2:11.

56. Snijders TAB, Bosker RJ.
Multilevel analysis: an introduction to basic and advanced multilevel modeling.
London: Sage Publications; 1999.

Table 6: Change in smoking, exercise, nutrition, BMI from baseline to 6 month survey

	Immediate intervention clusters	Wait-list control clusters	Overall
SMOKING			
Change in % 'Yes'			
EXERCISE			
Exercise >= once weekly Change in % 'Yes'			
Change in minutes spent excercising weekly mean, SD median , IQR			
NUTRITION			
Change in Fast food and snacks per week mean, SD median , IQR			
Change in Servings of fruit per day mean, SD median , IQR			
Change in Servings of vegetables per day mean, SD median , IQR			
Change in Sweetened beverages per day mean, SD median , IQR			
Change in Snack chips or crackers per week mean, SD median , IQR			
Change in Desserts and other sweets per week mean, SD median , IQR			
BMI			
Change in BMI mean, SD median, IQR			

Appendix 4: Table of eligible Chronic Disease Prevention and Screening actions / activities

Original identification number in BETTER SQUID table*	CDPS action / activity
1	fasting blood sugar or HgB A1C screen
3	Blood pressure screen
4	Blood pressure monitor
6	Measurement of low density lipoproteins
10	Screening mammography
11	Colorectal screening
12	Cervical screening / pap smear
13	BMI screening
14	Waist circumference measurement
15	Weight control
16	Referral for BMI > 25
18	Smoking cessation
19	Smoking cessation referral
21	Alcohol control
22	Alcohol control referral
24	Physical activity >= 90 minutes
25	Physical activity referral
27	Healthy diet score
28	Nutrition referral

* some actions / activities which were eligible in the original BETTER trial are deleted because they consisted of entry of information into electronic medical records, or depended on access to such records. We are preserving the original numeric identification of the remaining actions / activities.

Appendix 5: Brief Action Planning as the approach to prevention practitioner nurse BETTER intervention delivered in meeting with participant, incorporating information self-reported by participant, using principles of health coaching, shared-decision making, and motivational interviewing

The Brief Action Planning Guide

1 Mar 2014

A Self-Management Support Tool for Chronic Conditions, Health and Wellness

Brief Action Planning is structured around 3 core questions, below. Depending on the response, other follow-up questions may be asked. If at any point in the interview, it looks like it may not be possible to create an action plan, offer to return to it in a future interaction. Checking on the plan is addressed on page 2. Question #1 of Brief Action Planning is introduced in clinical interactions after rapport has been established.

1. Ask Question #1 to elicit ideas for change. "Situation" may be substituted when appropriate.
   "Is there anything you would like to do for your health in the next week or two?"

   a. If an idea is shared and permission received, specify details as they apply to the plan. (Help the person make the plan SMART - Specific, Measurable, Achievable, Relevant and Timed).

      "Many people find it useful to get very specific about their plan. Would that work for you?"
      With permission, proceed.
      "What?" (type of activity)
      "When?" (time of day, day of week)
      "Where?"
      "How often/long/much?" (often: once, three times, five times; long: minutes, days; much: servings, meals)
      "When would you like to start?"

   b. For individuals who want or need suggestions, offer a behavioral menu.

      i. First ask permission to share ideas.
      "Would you like me to share some ideas that others I've worked with have tried?"

      ii. Then share two to three ideas ALL AT ONCE. The ideas are not too specific, relevant to their goal and varied.
      "Some people I have worked with have _____, others have had success with _____ or _____."

      iii. The last idea is always one of their own. Then ask what they want to do.
      "Do any of these ideas work for you, or is there an idea of your own that you would like to try?"

      iv. If an idea is chosen, specify the details in order to make the plan SMART (1a above).

   c. After the individual has made a specific plan, elicit a commitment statement.
      "Just to make sure we both understand the details of your plan, would you mind putting it together and saying it out loud?"

2. Ask Question #2 to evaluate confidence. The word "sure" is a synonym for the word "confident."

"I wonder how sure you feel about carrying out your plan. Considering a scale of 0 to 10, where '0' means you are not at all sure and '10' means you are very confident or very sure, how sure are you about completing your plan?"

   a. If confidence level $\geq$7, go to Question #3 below. ***"That's great. It sounds like a good plan for you."***

   b. If confidence level <7, problem solve to overcome barriers or adjust plan. Explain the reason to boost confidence.
      "5 is great. That's a lot higher than 0, and shows a lot of interest and commitment. We know that when confidence is a 7 or more, people are more likely to complete their plan. Do you have any ideas about what might raise your confidence to a 7 or more?"

   c. If they do not have any ideas to modify the plan, ask if they would like suggestions.
      "Would you like to hear some ideas from other people I've worked with?"

   d. If the response is "yes," provide two or three ideas (behavioral menu). Often the following menu applies:
      "Sometimes people cut back on their plan, change their plan, make a new plan or decide not to make a plan. Do you think any of these work for you or is there an idea of your own?"

   e. If the plan is altered, repeat step 1c and Question #2 as needed to evaluate confidence with the new plan.

3. Ask Question #3 to arrange follow-up or accountability.
   "Would it be useful to set up a check on how it is going with your plan?"
   If they want to check, make the follow-up plan specific as to day, time and method (with themselves, with another via phone, email, in person, etc.)

Checking on Brief Action Planning

1. First ask, ***"How did it go with your plan?"***
    a. If they completed their plan, recognize (affirm) their success.
    b. If the plan was partially completed, recognize (affirm) partial completion.
    c. If they did not try to do their plan, say, ***"This is something that is quite common when people try something new."***
2. Then ask, ***"What would you like to do next?"***
    a. If the person wants to make a new plan, follow the steps on page 1. Use problem solving and a behavioral menu when needed.
    b. They may want to talk about what they learned from their action plan. Reinforce learning and adapting the plan.
    c. If the person does not want to make another action plan at this time, offer to return to action planning in the future.

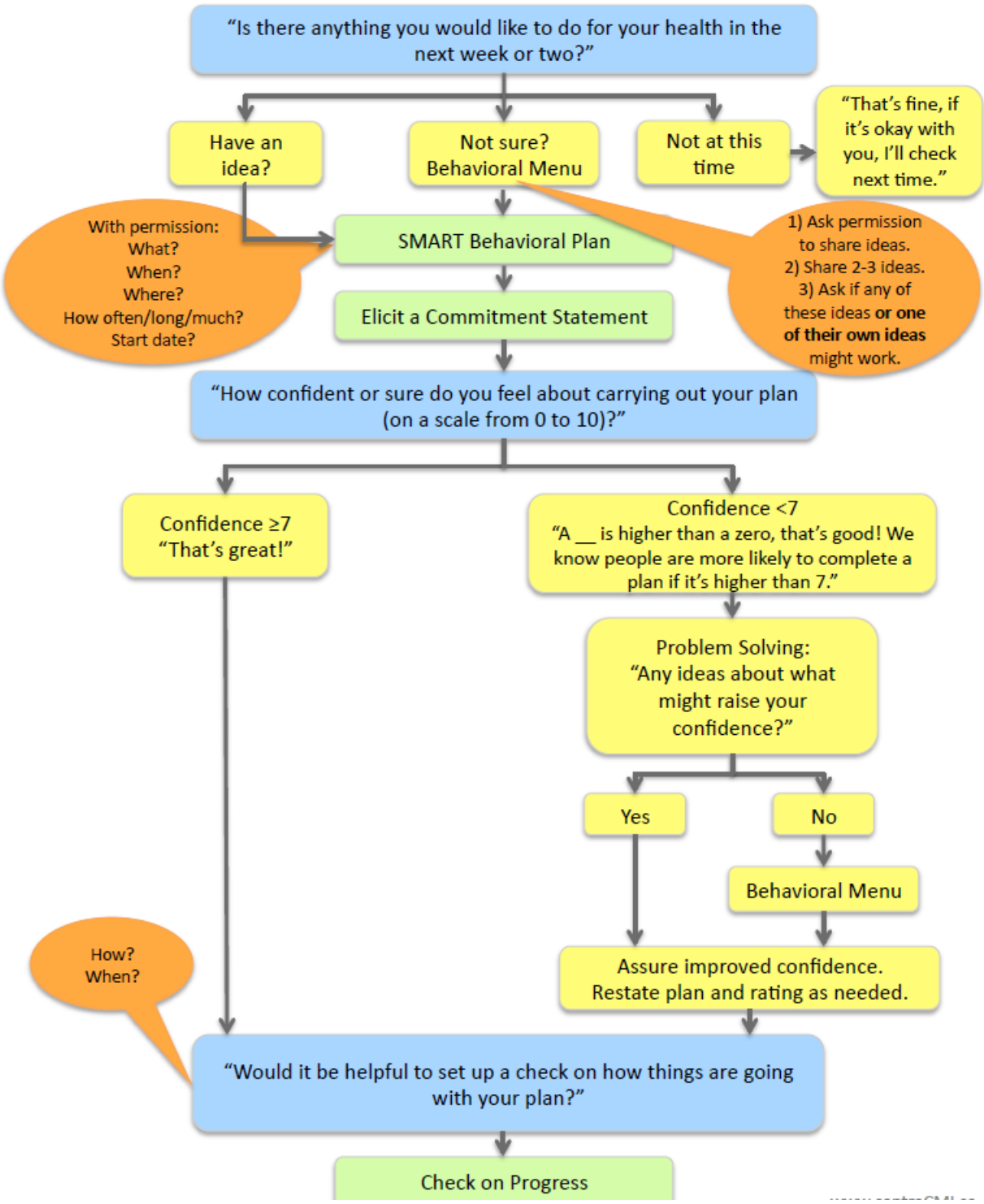
The Spirit of Motivational Interviewing

The Spirit of Motivational Interviewing underlies Brief Action Planning.

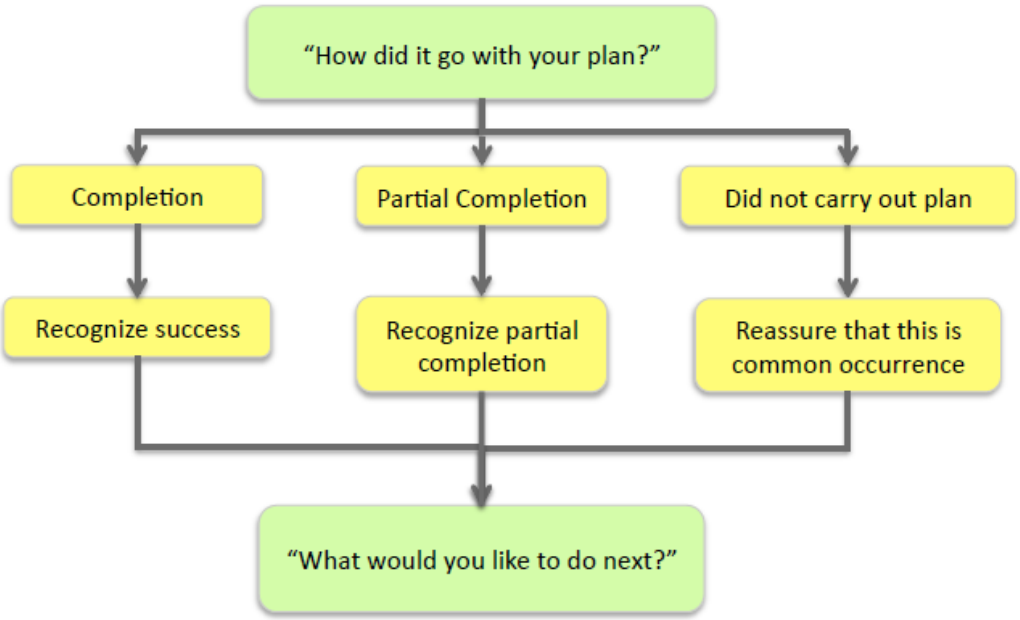
1. Compassion: Actively promote the other's welfare.
2. Acceptance: Respect autonomy and the right to change or not change.
3. Partnership: Work in collaboration.
4. Evocation: Ideas come from the person, not the clinician or helper.

Brief Action Planning Flow Chart

Developed by Steven Cole, Damara Gutnick,
Connie Davis, Kathy Reims



Checking on the Brief Action Plan



The Spirit of Motivational Interviewing is the foundation of Brief Action Planning

Compassion
Acceptance
Partnership
Evocation

Appendix 6: Steps to Adapt the BETTER Intervention (adapted from the ADAPT-ITT Model: Phases and Methods (Wingood and DiClemente, 2008))

Phase	Method
1. Assessment (Who is the new target population?)	1. Conduct small group meetings with: a) Members of the public potentially eligible for BETTER b) Prevention Practitioners (PPs), Nurse Practitioners (NPs) c) Community stakeholders 2. Summarize results of meetings
2. Decision to Adapt (Which (if any) components of BETTER will be adapted?)	1. Convene methods working group to review evidence from updated literatures searches and review results of interviews 2. Decide BETTER components to be adapted (if any)
3. Administer pilot test of existing BETTER tools (How do members of the public who are eligible for BETTER perceive the tools and intervention?)	1. Assessed during small group meeting in Phase 1 (above)
4. Production (How will the adapted BETTER intervention be produced and who will document adaptions?)	1. Develop adaptation plan 2. Produce adapted BETTER (first draft) 3. Document adaptation
5. Topic Experts (Who can help adapt BETTER?	1. Identify additional experts if needed 2. Involve experts in the adaptation plan
6. Integration (What will be included in the adapted BETTER?	1. Second iteration of adapted BETTER (if needed)
7. Training (Who needs to be trained in BETTER?)	1. Train Prevention Practitioners and Nurse Practitioners in adapted BETTER
8. Testing (Was the adaptation successful?)	1. test adapted BETTER 2. Assess success of adaptation via focus groups or interviews and analyze results

Appendix 7: Team of investigators

Lawrence Paszat, PI, Senior Scientist, Institute for Clinical Evaluative Sciences (ICES), Associate Professor, Dalla Lana School of Public Health, University of Toronto.

Aisha Lofters, *Co-PI,* CCSRI Junior Investigator*, Co-PI for primary care and BETTER intervention,* Assistant Professor of Family and Community Medicine, University of Toronto

Andrew Pinto, *Co-PI for primary care and for public health (jointly qualified)* Assistant Professor of Family and Community Medicine, and Dalla Lana School of Public Health, University of Toronto.

Mary Ann O'Brien, *co-PI for participatory research methods, qualitative data collection and analysis*, and KT. Assistant Professor of Family and Community Medicine, University of Toronto

Rinku Sutradhar, *co-PI for biostatistics*, Senior Scientist at ICES, and assistant professor of biostatistics, Dalla Lana School of Public Health. University of Toronto

Peter Selby, co-PI for smoking cessation and participatory research methodology, Professor, University of Toronto

Eva Grunfeld, co-investigator for methodology of BETTER, mentor to Aisha Lofters and Mary Ann O'Brien, Professor, University of Toronto

Donna Manca, co-investigator for primary care and for methodology of BETTER, participatory research methodology, qualitative analysis. Associate Professor, Department of Family Medicine, University of Alberta.

Frank Sullivan, mentor to Andrew Pinto, Professor of Community and Family Medicine, University of Toronto

Rick Glazier, mentor to Andrew Pinto, Senior Scientist (ICES). Professor of Family and Community Medicine, University of Toronto

Peter Donnelly, *co-investigator* Chief Executive Officer, Public Health Ontario

Linda Rabeneck, *co-investigator,* Senior Scientist ICES, Vice-president, Prevention and Cancer Control, Cancer Care Ontario.

Nancy Baxter, *co-investigator,* Senior Scientist ICES, Professor of Surgery, and Professor, Dalla Lana School of Public Health, University of Toronto.

Jill Tinmouth, *co-investigator* Scientist ICES, Assistant Professor, U Toronto, Lead Scientist, Colorectal Screening Program, Cancer Care Ontario.

Nicolette Sopcak, co-investigator, University of Alberta.

Robert Kyle, *co-investigator* Commissioner and Medical Officer of Health, Durham Region Health Department, Vice Chair of the Board, Public Health Ontario.

Mary-Anne Petrusiak, *co-investigator* Epidemiologist, Durham Region Health Department.

Jean Nesbitt, *co-investigator* Director, Public Health Nursing and Nutrition, Chief Nursing Officer, Durham Region Health Department.

Betty Wall, *co-investigator,* Program Manager, Durham Region Health Department.

Regina Elliott, co-investigator, Program Manager, Durham Region Health Department.

Appendix 8: Required contracts

Required contracts:

1. Sunnybrook Research Institute and Durham Region Health Department

-primary contact: Ms Becky Wall, becky.wall@durham.ca

-data custodian: Medical Officer of Health Dr Robert Kyle, robert.kyle@sympatico.ca

2. Sunnybrook Research Institute and Applied Health Research Centre, St Michael's Hospital

-primary contact for all issues: Ms Judith Hall, hallju@smh.ca

3. Sunnybrook Research Institute and Department of Family Medicine, St Michael's Hospital

-primary contact for all issues: Dr Aisha Lofters MD PhD, aisha.lofters@utoronto.ca

4. Sunnybrook Research Institute and Department of Family and Community Medicine, University of Toronto

-primary contact for all issues: Julia Baxter, family.healthcare@utoronto.ca

APPENDIX 9: Data security, privacy, confidentiality and management at the Applied Health Research Centre, St Michael's Hospital

Database Security Summary

The Applied Health Research Centre (AHRC), an academic research organization based at St Michael's Hospital, will create web-based electronic database application. Data will be entered into encrypted tablet computers by research staff of the Health Department, Durham Region, and securely transfered by WIFI to AHRC. All study data will be securely stored on local servers at St Michaels Hospital throughout the duration of the study and for up to 10 years after the study is complete. All study subjects will be identified in the database by a unique study ID number. Linkages between the patient name/contact information and the study ID will be retained at Health Department, Durham Region, and not shared. Data will only be accessible by authorized study site personnel and authorized central AHRC personnel, and the following research staff at the Health Department, Durham Region: research assistant, prevention practitioners, nurse practitioner. Authorized personnel receive a username and password which is unique, and database access is controlled by AHRC in collaboration with the Principal Investigator.

Physical Access and Security

The application will be hosted locally in St. Michael's Hospital's secure data centers and has dedicated IT, database, application, and build support personnel. The SMH data centre infrastructure has several features in place to enhance the security of data, prevent data loss and mitigate downtime. These include:

- Duplicate Internet Service Providers (ISPs)
- Infrastructure distributed between two data centres
- Virtualization for added redundancy
- Data centres are accessible by designated IT staff only
- Access is logged through RFID card access and through a physical sign in page
- Redundant UPS' for backup power
- Redundant cooling systems
- Inert gas based fire suppression system

Data will be stored on the local Storage Area Network (SAN) and will be backed up regularly and stored off-site. The data centre is designed such that there are daily backups made of all critical data. In addition, the backups are stored both locally, as well as at a remote off-site location, in the case of catastrophic failure at one location. With limited access privileges, 24 hour security, and around-the-clock monitoring, the data centre is highly secure.

Logical Access and Security

The servers are accessible by designated IT staff only for administration and maintenance purposes. The database application will be accessible by registered (through AHRC) users only, who are restricted to accessing the projects that they are assigned to. The database application will use standard authentication mechanisms to ensure only registered users can access the system, will ensure only explicitly specified users can access any particular project and data, and furthermore, will provide customizable user access for each project with controls that can be used to restrict users to write or read-only privileges on a form-by-form basis. Transmitted data will be secured through the use of TLS certificates that encrypt all data sent to and from the server.