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9 Patient-Centred Innovations for Persons with Multimorbidity: funded evaluation protocol

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3 Abstract

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5 Background: The high prevalence of multimorbidity (MM) requires rethinking the system of
6 health care. The overarching goal of this protocol is to build on existing structures and find and
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8 evaluate patient-centred innovations relevant to MM.
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15 Methods: The protocol describes two proposed multi-jurisdictional (Quebec and Ontario),
16 concurrent triangulation, mixed methods studies. In both provinces, a qualitative descriptive
17 study will be used to explore innovations in patient-centred MM care. The two randomized
18 controlled trials, one in each province, will evaluate the innovations in a wait-list controlled
19 design using patient reported outcomes, with an additional propensity matched control group
20 using health administrative data. Patients will be 18-80 years, with three plus chronic conditions.
21
22 The innovations have elements of: relevance to multimorbidity care; patient-centred
23 partnerships; and integration of care. Primary outcomes measures will be two patient reported
24 outcomes: patient education (HeiQ), and self-efficacy (SEM-CD). Secondary outcomes will
25 include: health status (SF-12); quality of life (EQ5D); psychological distress; health behaviours;
26 and costs of care.
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43 Interpretation: This protocol describes a mixed method study in each of two jurisdictions. The
44 studies will answer the questions of what innovations work and how they work for patients,
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46 health care professionals and policy-makers.
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50 Trial Registration: ClinicalTrials.gov Identifiers: NCT02789800 (Quebec Trial); NCT02742597
51 (Ontario Trial).
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Introduction:

This protocol on Patient-Centred Innovations for Persons with Multimorbidity (PACE in MM) describes a mixed-methods study, in two Canadian jurisdictions (Quebec and Ontario), evaluating complex interventions to improve patient-centred outcomes of persons with multimorbidity. The protocol was funded as a Team Grant in the Community-Based Primary Health Care Signature Initiative of Canadian Institutes of Health Research (CIHR), grant number 01247-000. The research program described herein is called PACE in MM.

Background and Literature:

The PACE in MM team will identify innovations with the following goals: to realign care toward multimorbidities rather than the single diseases, an approach known to be effective [1-12]; to focus care on the patient in context versus only on the disease, an approach found to have an impact on improving patient health [13], decreasing costs [14] and mitigating the deleterious effects of deprivation [15, 16]; and to improve integration and coordination of the system of health care [17].

In Canada, a considerable number of innovations have been mounted based on the Chronic Care Model [18-20], self-management programs [21] and primary care renewal [22], but very few of these have been described and only a minority of these have been evaluated [23].

Therefore, it is timely to identify such innovations and to evaluate whether or not they are effective and how they are effective.

The Protocol:

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3 This protocol describes a concurrent triangulation, mixed-methods study [24], explained in a
4 diagram in Appendix 1, in two Canadian jurisdictions (Quebec and Ontario), evaluating two
5 complex innovative interventions to improve patient-centred outcomes of persons with
6 multimorbidity – the PACE in MM study. The methods will comprise both a qualitative
7 evaluation and a quantitative evaluation of interventions, each of which has different objectives.
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9 We provide methodologic details of each part separately.
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20 1. Qualitative Evaluation of the Interventions 21

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24 The qualitative evaluation will answer the following research questions: What are the
25 components of the two interventions to be used in the intervention study? What are the
26 contextual factors that may influence the content and effectiveness of the interventions? What
27 are the potential barriers to and facilitators of the interventions in their context? How do barriers
28 and facilitators apply to population subgroups including patients of different genders and
29 vulnerable patient groups? How do the interventions promote patient-centred care?
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41 *Methods and design:* 42

43 The Team will conduct a qualitative descriptive study of two specific interventions to explore the
44 process of the interventions and experiences of key stakeholders involved [25]. In-depth
45 individual interviews will be conducted by the qualitative research team consisting of co-
46 investigators, doctoral students and trained research staff, with the four types of stakeholders
47 involved in each intervention: a) decision-makers (n=10); b) primary care physicians (n=10-15);
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49 c) professionals conducting the intervention (n=10-15); d) purposive sample of patients with
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3 multimorbidity, participating in the intervention (n= 10) and their informal caregivers (n=10)
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5 [26]. The numbers of interviews are estimates and will be guided by the saturation of data [26].
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11 *Data collection:*

12 The in-depth individual interviews, lasting 30 to 60 minutes, will be conducted in person by the
13 qualitative research team at a location convenient to the participant. Interviewers will conduct a
14 semi-structured interview using a guide to allow for exploration of relevant factors such as how
15 contextual factors, barriers, facilitators and personal factors will inform program delivery, both
16 with respect to current goals and future scalability. An example of an interview guide is
17 presented in Appendix 2 but certain questions will be tailored to capture the experiences and
18 knowledge unique to each group. All interviews will be audiotaped and transcribed verbatim.
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32 *Data analysis:*

33 The data will be analyzed using an iterative and interpretative approach [27]. The verbatim
34 transcripts will be examined through both independent and team analysis occurring in a
35 concurrent manner to build and develop on the emerging themes. There will be three phases: 1)
36 each transcript will be independently reviewed and coded by all the qualitative research team to
37 determine the key concepts emerging from the data; 2) the researchers will meet to examine their
38 independent coding, which will culminate in a consensus on the coding template with themes
39 and sub-themes, repeating these meetings until all interviews will be analyzed; and 3) the
40 research team will review the overarching themes and identify exemplar quotes illustrating the
41 themes and sub-themes. In particular, data related to patient subgroups (different genders and
42 vulnerable populations) will be identified. The data management software NVivo 10 [QSR
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3 International's NVivo 10 Software] will be used to organize the coded data and identify exemplar
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5 quotes reflecting the central themes [28].
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10 2. Quantitative Evaluation of Effects of the Interventions 11 12 13 14

15 The detailed version of the evaluation framework below will be made available to initiatives
16
17 across Canada interested in performing their own evaluation with the guidance of the PACE in
18
19 MM program.
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25 *Trial design:* 26

27 The design will be a randomized controlled trial where the patient is the unit, with a delayed
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29 intervention assessing short-term effectiveness. There will be two parallel groups for each of two
30
31 trials, one in Quebec and one in Ontario, each with equal numbers of patients in the intervention
32
33 and control groups. The risk of contamination, where control group patients experience part of
34
35 the intervention, will be minimal because intervention group patients will be referred by the
36
37 family physician (FP) to receive the intervention, separate from usual FP care, with a different
38
39 constellation of providers; both groups will receive usual care by the FP.
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43 Follow-up measures with all patients will permit assessment of mid-term effects and Health
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45 Administrative data will assess long-term effects.
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50 *Setting:* 51

52 Two interventions will be identified, one in Quebec and one in Ontario, that are innovations
53
54 being rolled out in primary care practices. The Quebec site will be in the Saguenay region and
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3 the Ontario site will be in Toronto. The methods, presented below according to the SPIRIT
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5 guidelines [29], are for one site and will be duplicated in the second site.
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10 *Eligibility:*

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12 Eligible patients will be men and women aged between 18 and 80 years; cognitively intact and
13
14 literate; newly referred to receive the innovative intervention by their provider because of three
15
16 or more chronic conditions; and never before exposed to the intervention. The upper limit of 80
17
18 years is to avoid recruiting patients at risk of being institutionalized or dependent during the two-
19
20 year follow-up. For the purpose of this study, we will operationalize the definition of
21
22 multimorbidity using Fortin's list of 21 chronic conditions [30].
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29 *Interventions:*

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31 The Quebec and Ontario complex interventions chosen for this trial will have common elements:
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33 referral by the FP to the intervention; shared philosophy of care; team based care; external
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35 relations with community resources; provider training; and patient partnership. However, the two
36
37 selected interventions will differ because of differing policy environments, with the Quebec
38
39 intervention stressing a co-located team, shared Electronic Medical Record, and explicit
40
41 empowerment of the patient, but with the Ontario intervention serving a more complex patient
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43 and his/her presence at the interdisciplinary team meeting where the care plan will be discussed
44
45 and mutually agreed. The Quebec intervention will be a program spreading across the Saguenay
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47 region called DIMAC 02 (Démarche Intégrée en Maladies Chroniques région 02) for patients of
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49 low-moderate complexity. A nurse will coordinate interdisciplinary care by relevant providers
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51 such as a kinesiologist, nutritionist and other primary healthcare professionals including
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3 motivational and self-management support over 4 months as well as a knowledge reactivation
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5 appointment in the following year. The Ontario intervention will be part of the Health Links
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7 Initiative for patients of moderate-high complexity, called TIP/IMPACT Plus (Telemedicine
8
9 Impact Plus). A nurse will coordinate a unique constellation of providers for each patient
10
11 including several medical disciplines such as family medicine, internal medicine and psychiatry,
12
13 as well as other interprofessional providers such as physiotherapy, occupational therapy, social
14
15 work, pharmacy, dietician, and home care. The providers and the patient will meet for 1.5 to 2
16
17 hours for a case conference where issues will be discussed and a mutually agreed care plan
18
19 constructed with patient input. Follow-up will be by the FP and nurse.
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22 Data will be collected to describe the elements of the interventions that each patient experienced.
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25 Concomitant care will be expected, permitted and measured by an adaptation of a valid measure
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27 by Browne et al. [31].
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34 *Participant Timeline:*

35
36 Patient participant time line in the trial is shown in Figure 1. Eligible patients agreeing to
37
38 participate will complete questionnaires at baseline (T1) collecting the sociodemographic data
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40 and baseline measures, which will be used to document equivalence between groups (groups are
41
42 defined below). Effectiveness will be assessed using three strategies.
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46 a) To measure short-term effects (4 months), a randomized controlled trial (RCT) design with a
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48 delayed intervention will be used [32]. Eligible patients will be randomized after consent to
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50 receive either the intervention within a short period of time (Group A) or 4 months later (Group
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52 B), ensuring an equal distribution of sex in each group; self-reported telephone questionnaires
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54 will be completed at baseline (T1) for all participants, 4 months after the end of the intervention
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3 for group A (T2) and 4 months after baseline for control group B (T2). This will constitute the
4
5 short-term measure of effectiveness of the intervention whose primary outcome measures are
6
7 shown in Table 1. Group B will then receive the intervention, See Figure 1.
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10 b) To measure the mid-term effects (one year) on patient-reported outcomes, a repeated measures
11
12 study will be conducted combining Groups A and B together. The patients will complete the
13
14 same questionnaire 12 months after the end of the intervention (T3).
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17 c) To measure mid-term (T3) and long-term effects (T4 after 2 years) on health services
18
19 utilization and cost, all patients (Groups A and B) will provide consent to give access to their
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21 health administrative (HA) data. HA data from each province separately will be used to collect
22
23 and evaluate comprehensive health care utilization from patients in both Groups A and B. A
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25 matched sample of non-participating individuals will be identified using HA data. A sampling
26
27 population will be created including all individuals meeting study eligibility criteria and cared
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29 for in a separate health region with similar health system (acute, primary and secondary care)
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31 supply characteristics.
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39 An index date will be set for all patients in the sampling population based on the distribution of
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41 enrolment dates in the intervention Groups. A propensity score will be calculated by merging the
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43 intervention groups with the sampling population and predicting likelihood of enrolment in the
44
45 intervention groups using age, sex, income quintile, diagnoses and health system utilization prior
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47 to enrolment as predictors. Individuals from Groups A and B will then be matched to a control
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49 Group C using sex, age, enrolment/index date (+/- 3 months) and the (predicted) propensity score
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51 within a caliper of 0.2 of the standard deviation of the propensity score. After establishing
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53 balance on measured covariates in the intervention and propensity-matched control groups, a
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3 differences-in-differences method will be used to compare outcomes in the pre versus the post-
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5 intervention period for the intervention versus the control patients.
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10 *Variables and outcome measures:*

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12 The short-term covariables and outcome measures are shown in detail in Table 1.

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14 The variables fall into five categories:

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17 1. Sociodemographic characteristics: include sex, gender, age, education, family income,
18 marital status, occupation, housing and number of persons living under the same roof.
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- 20
21 2. Primary care context variables: refer to type of PC organization in which the intervention
22 occurs (solo or group practices, Family Health Team Ontario / Family Medicine Group
23 Quebec, Community Health Centre, Teaching Unit/Academic Centre).
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30 3. Main covariables of interest: are the three innovations: self-reported multimorbidity
31 (measured by the Multimorbidity Assessment [33]); patient-centred partnership (Patient
32 Perception of Patient-Centredness Scale [34-36]); and Patient-centred coordination (the
33 Patient Perceptions of Transitions in care, adapted by our Team from Coleman) [37]).
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40 4. Primary outcome measures: are the Health Education Impact Questionnaire (HeiQ) that
41 provides a broad profile of the potential impacts of patient education interventions [38]
42 and the level of perceived disease-management self-efficacy using the 6-item Self-
43 Efficacy for Managing Chronic Disease (SEM-CD) [39].
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49 5. Secondary patient perceived outcomes: will be the SF-12 as a measure of health status
50 [40] and the EQ5D as a measure of Quality of Life [41]. The Kessler psychological
51 distress scale K-6 will measure psychological distress [42]. We will also use a
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3 Finally, HA data will also be used as secondary outcomes to compare health care utilization and
4 cost before and after the intervention. HA data will include emergency department visits,
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6 avoidable hospital admissions, readmissions, time to first primary care visit after emergency
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8 department visit and continuity of care. Permission will be sought from appropriate authorities in
9
10 each province to access the HA data.
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17 *Methods:*

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19 Patients referred by the primary care provider will be contacted by phone by a research assistant
20
21 to assess eligibility and obtain informed consent. After completing the baseline questionnaire and
22
23 sociodemographics with the patient, the research assistant will open a sealed envelope containing
24
25 the group assignment (intervention or control). The sealed envelopes will have been randomly
26
27 sequenced.
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31 Cards will be prepared; half with "Intervention" and half with "Control" printed on them. Prior to
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33 being placed into opaque envelopes and sealed, carbon paper will be overlaid on top of the
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35 allocation cards and an extra layer of cardboard placed behind the cards rendering them
36
37 impenetrable to light. The envelopes will be ordered according to a random number sequence
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39 and then sequentially numbered on the outside such that the number is transferred to the
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41 allocation card. These numbers will be participant study ID numbers. Envelopes will be opened
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43 sequentially with each enrollment only after participant names are written on the envelope and
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45 subsequently transferred by carbon copy to the allocation card. In this way simple randomization
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47 is achieved with adequate concealment and an audit trail is created.
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51 Research staff who did not participate in preparing the envelopes or allocation sequence will
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53 confirm eligibility, enrol participants, perform informed consent procedures, administer the
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3 baseline questionnaire, write patient name on the outside of the envelopes prior to opening, open
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5 the envelopes, and reveal randomization assignment to patient. Results will be recorded in a
6
7 master list of participants. Allocation concealment is not feasible. Blinding is neither feasible nor
8
9 necessary for this trial as both patients and health care providers need to know who is involved in
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11 each group as they both participate actively in the intervention.
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17 *Data Collection:*

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20 Three types of data will be collected and managed: data on referral and consent collected at the
21
22 intervention sites; data on covariables, primary and secondary outcomes (i.e. patient reported
23
24 outcome measures) collected by the PACE in MM research assistants; and data to allow linking
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26 with HA data in ICES in Ontario and RAMQ in Quebec.
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32 *Data Management:*

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34 Patient information on referral and consent that needs to flow between intervention settings and
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36 PACE in MM research team will use secure file transfer, secure email, or secure fax. Contact
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38 forms that physicians use to consent patients for PACE in MM research team contact, will be
39
40 shredded at the site once transferred. In Quebec, the referral information is kept in patient's
41
42 research file. TIP/IMPACT Plus and DIMAC02 nurses and other professionals will maintain
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44 their normal patient records for patients who participate in the intervention and observe their
45
46 institutional privacy policy for these documents.
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51 Personal information needed to allow linking with HA data will include patient name, address,
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53 phone number, date of birth, list of diagnosed conditions, and OHIP/RAMQ (Régie de
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55 l'assurance maladie – Québec) (Health Card) number. This participant information and the
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3 outcome data will be stored in separate files on secure institutional drives. Hard copy data of
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5 patient questionnaires, signed paper letters of information and consent forms will be stored in
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7 locked filing cabinets and data entered into protected electronic files. PACE in MM sites
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9 (Western University in Ontario and Sherbrooke University/CIUSSS du SLSJ) are committed to
10
11 providing an environment that protects the privacy and security of information and electronic
12
13 resources. Information and data management term of references and policies are adopted in each
14
15 site. Access to the files and the ability to link the participant information when necessary (for HA
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17 data linkage and participant follow up) will be monitored by the Principal Investigators and
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19 PACE in MM Research Coordinators.
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27 Qualitative interviews will be recorded as audio files and transcribed verbatim using secure file
28
29 transfer. Interview participants will be given a number prior to transcription. A master list of
30
31 participant name and interview number will be held in a separate password protected file on the
32
33 server and a physical copy locked in a secure cabinet.
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36 All data will be kept for 7 years in Ontario and 25 years in Quebec following study completion.
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38 At the end of 7/25 years, transcripts and any paper reports will be shredded and electronic data
39
40 files will be purged with the assistance of Information Services.
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43 Personal health information being released to a third party would be associated with minimal
44
45 risk. All measures will be taken to keep this information protected. If personal health information
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47 were inappropriately released, the investigators would stop the study and contact the Privacy
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49 Office and Research Ethics Boards to help manage the situation.
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3 Local standard does not require a Data Monitoring Committee but as part of the overall PACE in
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5 MM project there is governance through a Measurement Committee along with health care
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7 provider and patient advisory groups.
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10 All investigators will have access to complete data sets. Analysed data and results will be made
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12 available to local sites and interested participants upon publication of results. De-identified
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14 subsets of data will be transferred upon request to health care providers at participating
15
16 institutions and they will be responsible for pursuing additional ethics approval as required.
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22 *Data analysis:*
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24 We will first describe participants' baseline characteristics in each group and compare among
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26 groups. To evaluate short-term effect, Groups A and B will be compared on T2 scores with an
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28 analysis of covariance (ANCOVA) adjusted for T1 scores [44]. To document mid-term effects, a
29
30 repeated-measure analysis of variance will be used to study the evolution of continuous variables
31
32 collected 3 times [45]. Advice for the possible transformation of variables or the use of other
33
34 additional statistical analyses (e.g. other longitudinal and structural equation modeling analyses)
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36 will be sought from our collaborating biostatistician.
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43 Analyses assessing the differences by sex, gender and socioeconomic status will be performed.
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45 Health system costs in intervention and control groups will be evaluated by using amounts paid
46
47 to providers based on provincial fee schedules and cost-weighted utilization of institutions
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49 including hospitals and long-term care. Utilization records obtained from HA data will be
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51 multiplied by applicable cost weights (e.g. CIHI Resource Intensity Weights – RIWs and using
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53 CIHI Cost of a Standard Hospital Stay) [46]. The methods employed will model the individual
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3 patient-level costs incurred in the health system, using methods developed for costing using
4 administrative data [47]. Incremental resources in the intervention group will be identified and
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6 costed using applicable time/resource inputs and relevant wage rates following guidelines for
7
8 economic evaluation in health interventions [48].
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15 *Cross-jurisdictional comparisons:*
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17 The duplication of the evaluation in two provinces at the same time will allow for cross-
18
19 jurisdictional comparisons of the two primary outcomes, as well as health services utilization and
20
21 cost. Appropriate adjustment of costs will be made to obtain a valid comparison. Context
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23 variables related to the primary care organizations will be considered as potential confounders.
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29 *Sample size and effect size:*
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31 A sample size has been estimated for each individual component of this evaluation framework.
32
33 The required sample size for the randomized clinical trial was calculated for the two main patient
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35 outcome variables (the heiQ and the SEM-CD) with a two-sided $\alpha = 0.05$ and 80% power. First,
36
37 for continuous scores, 64 participants in each group will allow detection of medium effect size
38
39 (ES=0.5) [49]. But, for the heiQ, results are typically expressed as the percentage of patients
40
41 improving at least half a standard deviation, found in a previous study to be 35% [38]. Using a
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43 conservative scenario of improvement of 20% in the control group, 138 patients will be required
44
45 in each group to detect this 15% difference. Accounting for an anticipated drop-out rate of 15%,
46
47 326 patients will be randomized, 163 in each group in each province. For assessing the long-term
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49 effects in HA data, a ratio of 5:1 for the control Group C will provide 1630 matched patients in
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51 each province. With a population of this magnitude, we will be able to detect minimally a
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3 difference of 10% in health care utilization as for example the rate of emergency room visits
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5 (two-sided $\alpha = 0.05$ and 90% power). Moreover, since we have a limited set of characteristics for
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7 the controls, the ratio 5:1 will ensure that we have an average picture for each control.
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13 *Ethics:*

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15 Ethics review for the qualitative and randomized trial in Quebec was conducted by the Comité
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17 d'éthique de la recherche du Centre Intégré Universitaire de Santé et de Services Sociaux du
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19 Saguenay - Lac St-Jean, 2013-010. Ethics review for the qualitative study in Ontario was by
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21 Western University, 104191. Ethics review for the randomized trial in Ontario was conducted by
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23 Western University, 106921; Sunnybrook Hospital Toronto; University Health Network Toronto;
24
25 and Toronto East General Hospital. Neither the Co-Principal investigators nor the site leads have
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27 conflicts of interest to declare.
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31 Ancillary Care needed by participants will be provided by the FP referrer.
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37 *Dissemination:*

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39 The PACE in MM program intends to disseminate the results of this program of research widely.
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41 Qualitative and quantitative findings will be shared with patients, providers, partner decision-
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43 makers, and other researchers. Three provinces other than Quebec and Ontario are co-
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45 investigators and will participate in a scaling up components of the program: Nova Scotia;
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47 British Columbia; and Manitoba.
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3 *Authorship:*
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5 PACE in MM has an authorship policy for its co-investigators and does not intend to use
6 professional writers.
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12 Discussion:
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15 Driving innovation in health care to better manage urgent problems such as chronic disease
16 prevention and management is a high priority in Canada, for funders such as CIHR and for
17 policy makers. Other countries too are experimenting with innovations in chronic disease care,
18 with 18 interventions identified and evaluated in the latest Cochrane review, representing 5
19 countries. These interventions have shown mixed results and had low power, so PACE in MM's
20 contribution in this field has a great potential.
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32 This protocol sets out a way to identify and evaluate innovations. Policy-makers are part of the
33 PACE in MM research team; so integrated knowledge translation will be possible.
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39 The protocol outlines the way to achieve two key deliverables. The first is to illustrate cross-
40 jurisdictional comparisons of innovative chronic disease prevention and management programs.
41 The second is to provide a rigorous quantitative evaluation framework, that others may use,
42 which includes both: a) measures of patient experience; and b) HA and cost data.
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50 The proposed randomized trials have the potential to reveal whether the innovations work in
51 multimorbidity care. The qualitative studies have the potential to show how the innovations work
52 for patients, health care professionals and policy-makers.
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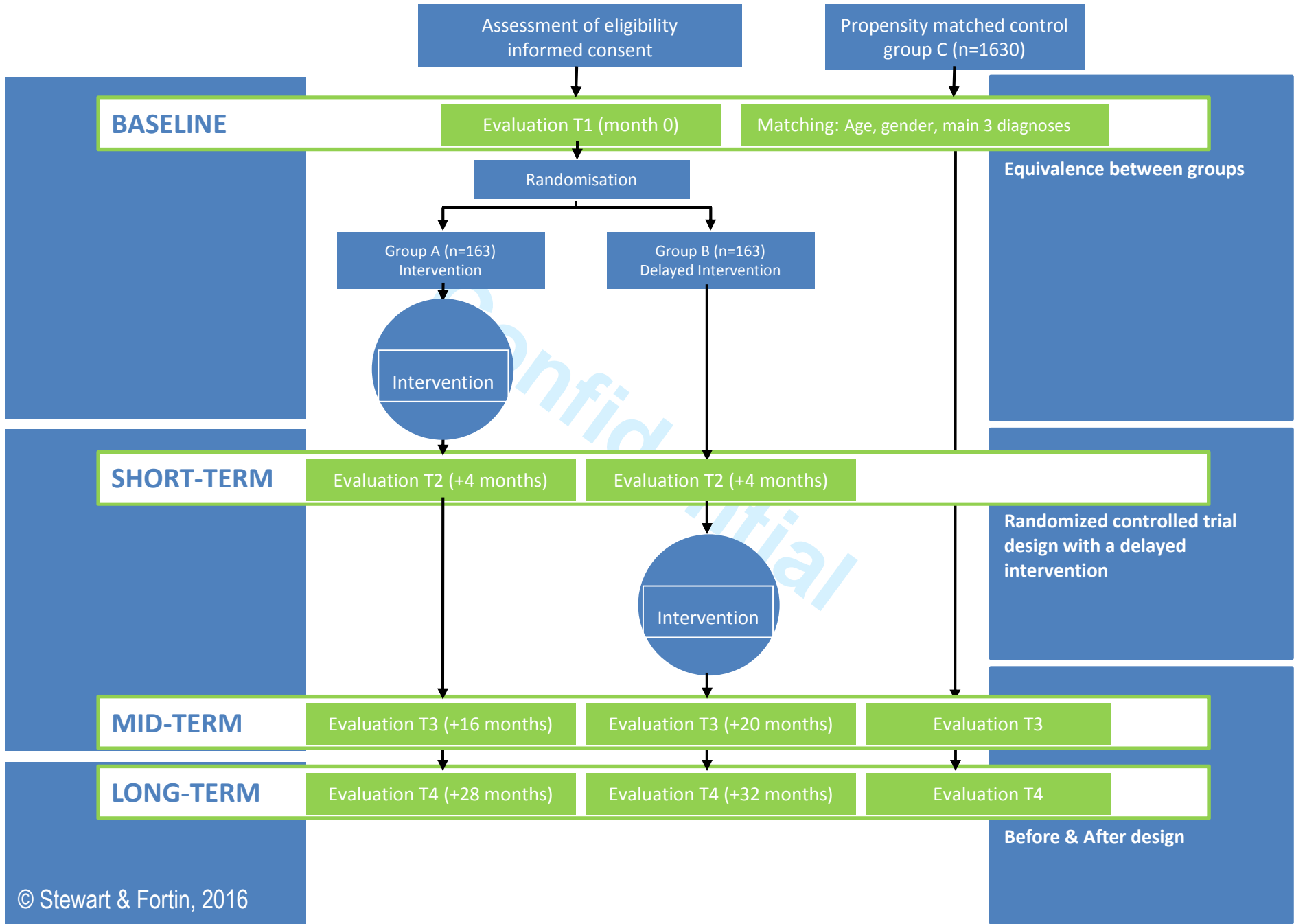
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Table 1. Covariables and Outcome Measures for the Randomized Controlled Trial of Short Term Effects

MEASURES	PSYCHOMETRIC PROPERTIES
The main covariables of interest	
MM21 <i>Multimorbidity</i>	The Multimorbidity 21 measure Validity: sensitivity 84.6%, specificity 84.3% compared to a quality of life measure; Test-retest Reliability: ICC of 0.88 and Cohen's Kappa 0.64; Inter-rater Reliability ICC 0.88 and Cohen's Kappa 0.79 [33]
Patient Perception of Patient-Centeredness Scale <i>Patient-centered Partnership</i>	14-item measure of patient perception of patient-centeredness of visits with health professionals. Reliability: Chronbach's alpha 0.71, n=315. Validity: Significant associations with SF-36 health status measure [34-36]
Patient Perceptions of Transitions in care <i>Patient-centered Coordination</i>	9-item questionnaire for patients. Items adapted from Coleman et al. Reliability: Cronbach's alpha of the Coleman measure: 0.93 [37]
Patient perceived primary outcomes measures	
HeiQ <i>Patient education program benefits such as empowerment</i>	The Health Education Impact questionnaire "Proxy of empowerment" Cronbach's alphas from 0.70 to 0.89 according to the domain; ≥ 0.80 for 7 out of 8 domains [38]
SEM-CD <i>Self efficacy</i>	The Self-Efficacy for Managing Chronic Disease scale: 6 items + 2 items from general scale. Reliability: Cronbach's alpha for SE-MCD: 0.91; for SE-general: 0.87 developed by the Stanford Patient Education Research Center [39]
Patient perceived secondary outcome measures	
SF-12v2 <i>Health status</i>	Multipurpose short-form generic measure of health status. Validity: Correlations (r) of 0.95 and 0.96 with the SF-36 for the physical and mental components respectively [40]
EQ-5D <i>Quality of life</i>	Intra-class correlation: EQ-5D Utility: 0.73, EQ-5D VAS: 0.70. Test-retest: 0.86 for group level coefficients and 0.90 for a coefficient derived from individual correlations [41]
K-6 <i>Psychological well-being</i>	Internal consistency: Cronbach's alpha: 0.89; Concurrent validity: correlated at $r=0.97$ with its equivalent, the K10; Discriminant validity: AUC: 0.89, 95 % CI: 0.88-0.90; Sensitivity: 0.36 (0.08), Specificity: 0.96 (0.02) [42]
BRFSS <i>Health behaviour</i>	Behavioural Risk Factor Surveillance System Questionnaire (eating habits, physical activity, smoking and alcohol consumption). Individual level test-retest reliability measures: Kappa > 0.60 for 19 demographic and risk factors, intermediate for food consumption measure (0.40-0.76), lowest for routine check-up and BP check in past two years (Kappa = 0.54 and 0.23) [43]

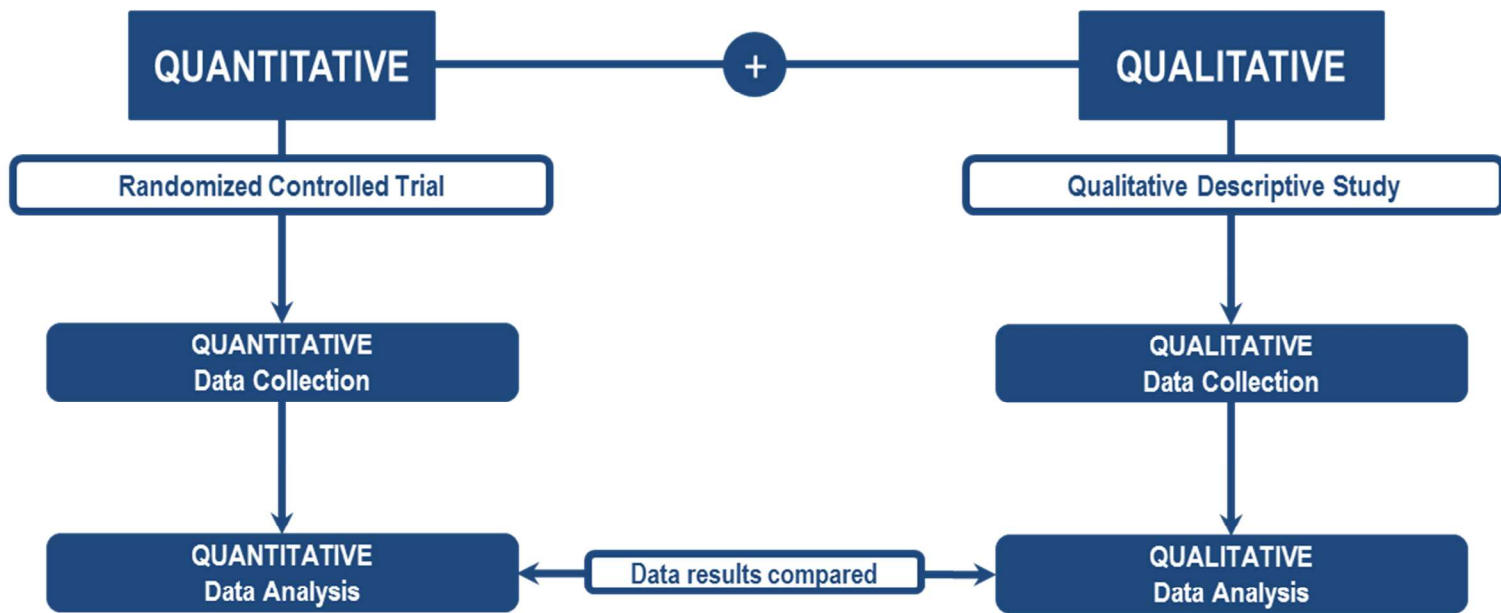
Figure 1: Quantitative Study in Each Province



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Appendix 1 Diagram of the Concurrent Triangulation Mixed-Methods Design*



* Adapted from Creswell 2003, page 214 [24]

Appendix 2

Interview guide for PACE in MM Objective 2 Qualitative Study

Healthcare Providers/Decision Makers

Thank you for agreeing to talk with me today. I am going to ask you about your experience here at X (location of the program). At this time, I'd like to remind you that this interview is audio recorded as per the Letter of Information.

First let me ask you some basic questions. What is your:

1. Age
2. Profession
3. Year graduated
4. Title of current position
5. How long have you worked here at X (program location)

The Program: Now we are going to talk about the program and its various components.

1. Can you describe the program and how are you involved?
2. What are your overall views on the program and does it meet your expectations?
3. In your opinion, what facilitates the program activities?
4. How do these facilitators influence the content and the effectiveness of the program?
5. In your opinion, what are the barriers you face with the program?
6. How do these barriers influence the content and the effectiveness of your program
(Probe: Poor health literacy, low socio-economic status)?
7. Are there any contextual factors with regards to this program that serve as facilitators or barriers (Probe: space, time, distance, organizational issues)?

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8. a) How do the services of your program assist patients in managing their multiple chronic diseases? Probes: How do they assist patients who are vulnerable (gender, low literacy, ethnic minority, low income, disabled)?
- b) In what ways has the program (either in implementation, access, or impact) differed for male and female patients if at all? Can you elaborate on your observations about this?
9. How would you describe the impact of the program on patients, their family, and other stakeholders? What is the impact on patients and their families who are more vulnerable?
10. How does the program enhance the patient motivation to take charge of their health and health care?
11. How does your program address the transition and coordination of care for persons with multiple chronic diseases? How do you address patients who are more vulnerable (gender, low literacy, ethnic minority, low income, handicapped)?
12. How do you know when you and your colleagues are providing patient centered partnerships?
13. How do you ensure a patient is a member of the care team? Probe: what ways can patients attending your program participate more in the decision of the way care is provided?
14. If your patient runs into problems or a crisis, what do you do? Can you provide an example when your patient ran into a problem or crisis? How did the program respond?
15. Would you call your group of providers a "team"? YES/NO
16. What helps your team/program and other providers work together?

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Probes:

Communication

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3 Leadership

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5 Differences of opinion

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7 Conflict resolution strategies

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10 17. What thoughts do you have about how this program can be sustained?
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12 18. What are your thoughts on how this program could be expanded and adopted by other
13 health care providers working with patients with multimorbidity?
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17 That concludes our formal interview. Is there anything you would like to add or explain? Thank
18 you.
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