The PR1MaC Study: a pragmatic randomised trial of the integration of chronic disease prevention and management services into primary care.

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Abstract

Background: Chronic disease prevention and management (CDPM) programs designed to improve patient outcomes are usually single-disease oriented. We evaluated an intervention adapting and integrating CDPM services targeting multiple diseases and risk factors (diabetes, cardiovascular disease, COPD, asthma, tobacco smoking, obesity, hyperlipidemia, carbohydrate intolerance, sedentariness). The intervention included: self-management support and health education, patient-centered and motivational approaches, and inter-professional collaboration.

Methods: A pragmatic randomised trial was used to evaluate the intervention. Self-management as a primary outcome was evaluated through the Health Education Impact Questionnaire (heiQ) that measures eight different domains. Secondary outcomes included: self-efficacy, health related quality of life (SF-12), psychological distress, and health behaviours.

Results: 332 patients were randomized (166 in both intervention and control groups) and evaluated after three months. The intervention group showed a reliable improvement in six of the eight heiQ domains: health directed behaviour (Relative Risk; 95%CI) (1.71; 1.13-2.59), emotional well-being (1.73; 1.07-2.79), self-monitoring and insight (2.40; 1.19-4.86), constructive attitudes and approaches (2.40; 1.37-4.21), skill and technique acquisition (1.70; 1.14-2.53), and health service navigation (1.93; 1.08-3.47). Improvement was also observed in the Physical Component Summary ($p = 0.017$) and the Single Index ($p = 0.041$) of the SF-12. The intervention group improved in fruit and vegetable consumption (odd ratio 2.36; 95%CI = 1.41 - 3.95) and physical activity (odd

ratio 3.81; 95%CI = 1.65 - 8.76). One-year improvement was maintained in the intervention group for several outcomes.

Interpretation: Adapting and integrating chronic disease prevention and management services into primary care settings yielded positive and promising results.

Trial Registration: ClinicalTrials.gov Identifier: NCT01319656

Running Head: Chronic disease management services in primary care

Introduction

Chronic conditions are the most common problems in health care and the leading causes of death globally [1]. Acute communicable diseases have given way to chronic conditions such as arthritis, diabetes, cardiovascular and respiratory diseases which will impose an even greater burden on the future [2]. The needs of these patients are usually complex and require difficult management. For this reason, many chronic disease prevention and management (CDPM) programs have been designed with the aim of improving outcomes in these patients. CDPM programs targeting diabetes [3-7], asthma [8, 9], heart diseases [10-12], depression [13-15], chronic obstructive lung disease (COPD) [16, 17], obesity [18, 19], kidney disease [20], dyslipidemia [21], hypertension [22], and chronic pain [23] have shown to be effective in improving outcomes such as hospital admissions, costs, adherence to medication, disease control, use of health services, quality of life and mortality. These studies have been based in different settings and were based on single diseases.

Interventions oriented around single diseases take little account of the multiple morbidities experienced by the majority of patients in primary care. To date, the appropriateness of using multidisciplinary professionals in the context of CDPM programs addressing several conditions has been little studied, and the few studies reported mixed but promising results [24-26].

This study introduces a pragmatic innovation involving adapting and integrating CDPM services for multiple diseases into primary care settings and proposes an innovative combination of strategies to evaluate the effects and implementation of this intervention in primary care practices. We wanted to test whether it was possible to implement an

intervention integrating multiple-disease oriented CDPM services into primary care settings. We hypothesized that patients receiving the intervention will report better self-management, empowerment and self-efficacy and will demonstrate reduced health risk behaviour. (ClinicalTrials.gov Identifier: NCT01319656) [27].

Methods

Settings and subjects

The study took place in eight primary care practices in the Saguenay region of Quebec, Canada. Patients were referred to the research team by their primary care providers to assess eligibility, obtain informed consent and receive the intervention. Patients had to be between 18 and 75 years of age and present at least one of the following chronic conditions or risk factors: diabetes, cardiovascular disease, COPD, asthma, tobacco smoking, obesity, hyperlipidemia, carbohydrate intolerance, sedentariness or any combination.

Intervention

Detailed information on the intervention is provided elsewhere [27]; we provide here only a short description of the main elements. The principles guiding the intervention were based on the following: self-management support and health education, a patient-centred approach, motivational approach and inter-professional collaboration. For each patient, the intervention started with a preliminary clinical evaluation by a trained nurse.

The nurse then designed an individualized intervention plan in collaboration with the patient that could include encounters with one or more CDPM professionals in the following disciplines: nursing, physical activity therapy, nutrition, respiratory therapy, and smoking cessation therapy. The intervention plan was rooted in the patient's objectives as identified at the first encounter but could be further adapted by any professional in each discipline involved, and could make use of the patient caregiver's perspective. Each intervention was supported by printed information and other educational material to help maintain patient engagement between visits. Intervention at the patient level: (a) was individualized and educational in nature; (b) was given over a three month period at the most, and (c) consisted of at least three individual encounters with trained CDPM professionals.

Study design

The effectiveness of this pragmatic intervention was assessed through a combination of three experimental designs.

Pragmatic Randomized Trial. Participants completed an initial set of questionnaires at baseline and socio-demographic data. Patients were then randomized to receive an immediate (Experimental Group A) or delayed intervention (Control Group B). To prevent selection bias, a rigorous randomization methodology process with allocation concealment was followed. Blinding was not achievable, as both patients and health care providers knew who was involved in each group.

Three months after baseline patients in both groups completed the second evaluation.

Before-and-after design. To document the effectiveness of the intervention at one year, patients in Group A were reassessed a third time, one year after baseline using the same measurement tools.

Quasi-experimental design. Finally, a quasi-experimental design with a comparative cohort was also used to evaluate one year effectiveness. All patients who received the intervention (Groups A and B) were included in this analysis. The control group (Group C) was from the PRECISE research program platform (www.programmeprecise.ca) [28]. The PRECISE program recruited a cohort of adults aged 25 to 75 years, from the geographic boundaries of four regions of the Quebec province (Canada). Patients from this observational cohort (2,198 subjects) were pair-matched with all patients in the present study (Groups A and B) by age (± 5 years), sex, number of chronic diseases, main diagnosis, and other diagnoses when possible. Groups were compared on the basis of changes over one year.

Variables and outcome measures

At baseline, we collected participant's socio-demographic data including gender, age, education, income, marital status, and occupation. We also measured the illness burden using the Disease Burden Morbidity Assessment (DBMA) tool [29, 30].

The main outcome, self-management, was evaluated via the Health Education Impact Questionnaire (heiQ) [31, 32] which provides a broad profile of the potential impacts of patient education interventions and is specifically designed to be applied across a large range of chronic conditions. The heiQ measures eight different domains related to self-management. Each domain is standardized to range from 1 to 4, and baseline and follow-

up data was compared to determine the achievement of meaningful changes in each domain (see Data analysis). The heiQ has high construct validity and very good reliability [32]. The development and validation of the heiQ, including the French version, is described elsewhere [32, 33].

Secondary outcomes used to assess the effectiveness of the intervention were: self-efficacy, health related quality of life, psychological distress, and lifestyle factors. *Self-efficacy* was evaluated using the 6-item questionnaire Self-Efficacy for Managing Chronic Disease (SEM-CD) [34, 35].

Health related quality of life (HRQoL) was measured using the SF-12 version 2 [36]. The measurement includes the components of physical functioning and mental health. We also calculated a preference-based single index of quality of life called SF-6D by applying a scoring method that contains six dimensions of the SF-12 [37]. Higher values indicate better health status in all measures of HRQoL.

Psychological distress was assessed using the Kessler psychological distress scale K-6 [38, 39]. Scores can range from 0 to 24; scores of 13 or higher were considered as presence of psychological distress. Finally, we used three self-reported lifestyle indicators: fruit and vegetable consumption, physical activity, and body mass index (BMI) derived from self-reported weight and height. The criteria for classifying participants as achieving recommended behavioural targets were the following: 1) consumption of five portions or more of fruit and vegetable daily (1 portion = 4 ounces or 125 ml); 2) being physically active (20-30 min. of exercise 4 times per week); and 3) normal BMI (18.5 – 24.9 Kg/m^2) [40]. All the above outcomes were measured at baseline, after three months, and after one year via self-reporting.

Sample size and statistical power

The required sample size of 326 participants for the randomized clinical trial was calculated for the main outcome (the percentage of patients improving on the heiQ) with a two-sided $\alpha = 0.05$ and 80% power and accounting for a drop-out rate of 15%.

Data analysis

Randomized trial. To evaluate meaningful individual changes in the heiQ domains, we used the 'classical reliable change index' with a cut-off of >1.65 [41]. For each of the eight domains of the heiQ, we compared the percentages of subjects with a reliable improvement in each group (A vs. B) using the relative risk (RR) with a 95% confidence interval (95% CI). This primary analysis was performed in intention-to-treat.

To evaluate intervention effects on quantitative outcome, we compared group A and B scores after three months with an analysis of covariance (ANCOVA) adjusted for baseline scores [42]. Cohen's d was the effect size used to indicate the standardised difference between two means. For dichotomous outcomes, we compared Groups A and B using a logistic regression analysis adjusted for baseline. Since there were only a few missing outcomes after three months (less than 5%), we undertook a "complete case" analysis [43].

Before-and-after design. To test the effectiveness of the intervention within Group A over a year, we used paired t-test for the continuous variables and McNemar's test for categorical variables.

Quasi-experimental design. Finally, for comparisons with Group C over a year, we used ANCOVA or logistic regression adjusting for scores at baseline, age and sex.

All data were analysed using the statistical package IBM SPSS Statistics 20. In all statistical tests, we tested for significance at the 5% level. Cohen's d effect size [44] was calculated with Microsoft Office Excel 2007 using the pooled standard deviation for the samples in the calculation.

The study received approval from the Research Ethics Board of the *Centre de Santé et de Services Sociaux de Chicoutimi*.

Results

Figure 1 shows the flow chart diagram for the three different experimental designs below. Table 1 shows the baseline demographics and clinical characteristics of participants for each group.

Randomized trial

The recruitment and follow-up periods started in November 2011 and ended in July 2012. A total of 481 eligible patients were referred by primary care providers; 144 patients received the intervention but refused to participate in the research. Five patients of the 337 who initially agreed to participate declined before completing the baseline questionnaires. The remaining 332 patients were randomized as follows: 166 in Group A (intervention group), and 166 in Group B (control group). Nine patients from Group A and five patients from Group B were lost to follow-up after three months. Therefore, 157

patients of Group A and 161 patients of Group B underwent the evaluation after three months.

HeiQ scores in Groups A and B at baseline and after three months are shown in Table 2. Mean absolute values after three months were significantly different from baseline in six of the eight domains of heiQ: health directed behaviour, emotional well-being, self-monitoring and insight, constructive attitudes and approaches, skill and technique acquisition, and health service navigation. The relative risk (RR) of a reliable improvement from baseline to three months in Group A compared to B for each domain of self-management is shown in Figure 2. Point estimates vary from 1.15 to 2.4 and the lower boundary of the 95% CI is higher than one in the same six domains of heiQ in which mean absolute values were different from baseline after three months.

With regard to other continuous variables (Table 3), differences in mean scores between Groups A and B were statistically significant for two HRQoL variables, the Physical Component Summary (PCS) and the single index of SF-12 (SF-6D). Results of the logistic regression analysis for the presence of psychological distress, recommended consumption of fruit and vegetables and recommended physical activity, are shown in Table 4. Odds ratios were significantly higher for Group A in fruit and vegetable consumption and physical activity.

Before-and-after design

A summary including the results for all variables of the before-and-after design in participants of Group A is shown in Table 5. The analysis included only those subjects with data at baseline, after three months, and after a year. After three months, changes in

all domains of the heiQ were significantly different from baseline, with an effect size ranging from small to medium (between 0.20 and 0.52). After a year, changes continued to be significantly different from baseline with the exception of the Health service navigation domain. Figure 3 shows the changes in each domain of the heiQ over a year. The percentage of patients in Group A who improved in different domains was between 16% (23/143) and 36% (50/140).

Quasi-experimental design

The 332 subjects in the present study were matched with the 332 subjects of the PRECISE (Group C) study by age, sex, number of chronic diseases, main diagnosis, and other diagnoses when possible. Demographic and clinical characteristics of Group C and PR1MAC participants at baseline are shown in Table 1. Table 6 shows the results over a year, with significant differences in the PCS and BMI, favouring the intervention.

Interpretation

Many CDPM programs using interdisciplinary teamwork have been described, but the vast majority have been focused on single diseases, and only a few have considered more than one disease. In the intervention that is object of this study, we adapted and implemented the integration of disease prevention and management services into primary health care for four chronic conditions and their risk factors. After three months, the intervention showed some benefit in six out of the eight domains of self-management measured by the heiQ, both in terms of absolute mean values and relative risk analysis, as compared with the control group. However, percentage of patients in Group A who

improved in different domains (Figure 3) was between 16% (23/143) and 36% (50/140), i.e. they were not the majority in any domain. Our interpretation of this is that there is still room for improvement and making the intervention more effective. Recently, Coventry and colleagues [45] published the results of a cluster randomised controlled trial for patients with depression and comorbid diabetes or cardiovascular disease in which the heiQ was used as a secondary outcome. As occurred in our study, Coventry and colleagues did not observe significant improvement in the domains "Positive and active engagement in life" and "Social integration and support".

The evaluation of secondary outcomes in our study also showed modest but beneficial effects of the intervention in fruit and vegetable consumption, physical activity, and the physical component of quality of life. After one year, improvements were still present, in general. BMI showed a modest but significant improvement after one year. Psychological distress did not change. This lack of change could reflect either that the length of the interventions was too short or that the elements behind this situation were not among those targeted by the intervention. The prevalence of recommended physical activity significantly improved at three months but then decreased over a year to a level equivalent to baseline. This may indicate a need to reinforce the message at follow-up. According to a recent systematic review, interventions to promote physical activity lead to improvements in physical activity at 12 months. Longer sustainability is unclear [46]. The Self-efficacy for Managing Chronic Disease score showed no significant difference between experimental and control groups. A closer look at the results of this variable showed that mean values were rather high at baseline in both groups with little room for improvement. The statistically significant improvement observed in the physical

component of quality of life of the experimental group was barely clinically important [47].

We are aware of only a few studies of multidisciplinary specialized professionals in the context of primary care practices. These studies were conducted in the context of single conditions including COPD and asthma [16, 48], metabolic syndrome [49], kidney failure [20], diabetes [50], blood pressure control [51], or people with risk factors [52]. Interventions were based on different approaches, mainly self-management support and patient education. The outcomes used varied greatly from one study to another and included the use of healthcare services, quality of life, various physiological indicators and risk factor modification. All studies reported positive results in their respective outcomes. We did not find any study in which interventions addressed more than one concurrent chronic condition, which is a situation frequently present in primary care [53, 54].

Implications for practice

This study demonstrated that it is possible to implement an intervention integrating chronic disease prevention and management services for several chronic conditions into primary care settings. Despite the short duration of the intervention, it was possible to observe positive results. Adding a few hours of contact with the patients after a few months from the initial intervention could potentially boost the positive effects for a longer period of time. As commonly observed in primary care, the majority of patients participating in the study had multimorbidity. This population could be specifically targeted in further studies. The intervention consolidated the central role of primary

health care professionals and their organization, while maintaining the natural proximity between the patient and their primary care clinic. In this regard, interventions: (a) were carried out upon referral from the primary care team; (b) allowed an exchange with the primary care team and were included in primary care medical records; (c) returned the responsibility of long-term follow-up to the primary care team. We think that it is appropriate to test the intervention in different care organizations.

Limits and strengths

Generalisability may be limited given the study eligibility based on selected conditions (type II diabetes, cardiovascular disease, COPD or asthma), or risk factors (smoking, obesity, hyperlipidemia, carbohydrate intolerance, and metabolic syndrome). However these patients are the norm in primary care.

Building an intervention using multiple CDPM professionals poses a challenge. There could have been some variation in the way these professionals provided the services despite the fact that they had similar training before starting the intervention.

The use of patient self-reported questionnaires for outcomes is also an issue. This method may have introduced some desirability bias but it is coherent with the use of a patient-centered approach. Finally, 30% percent of the patients referred by primary care providers to the research team declined participation in the research. The impact of this on the composition of the sample of participants is not known.

A strength of this study is that the pragmatic trial was conducted with patients as they present in the real world: all eligible patients were included and no patient was refused because of their disease burden or comorbidities like you would expect in most clinical

trials. Positive results in this context are highly significant. The use of a triple experimental design also allowed us to measure the outcomes from different lenses up to one year after the intervention, and to better adapt to the context of practice-based research.

Conclusion

The evaluation of an innovative intervention for adapting and integrating chronic disease prevention and management services, which addressed more than one disease or risk factor into primary care settings yielded positive and promising results. This type of intervention can surely be improved, and its introduction in the routine of primary care practice would help to achieve the primary care goal of high quality care for patients with chronic diseases.

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Authors' contributions

M Fortin, MC Chouinard, MF Dubois and M Bélanger identified the need for this study and contributed to its conception and design. J Almirall and T Bouhali conducted the analysis of data under the supervision and guidance of MF Dubois and M Fortin. MC Chouinard, M Bélanger and M Sasseville also contributed to the analysis and interpretation of data. All authors contributed to the first draft and had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to the writing and gave the final approval of the version submitted. M. Fortin takes responsibility for the integrity of the work as a whole.

Competing interests

All authors declare that they have no competing interests.

Other information

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Dr. Martin Fortin holds the Research Chair on Chronic Diseases in Primary Care.

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Table 1. Demographic and clinical characteristics of participants at baseline.

	Mean (SD)			
	PR1MAC	Group A*	Group B*	Group C
	n = 332	n = 157	n = 161	n = 332
Age (yr.)	52.5 (11.6)	52.8 (11.4)	52.9 (11.5)	54.0 (9.9)
Number of chronic diseases	4.9 (2.4)	5.1 (2.6)	4.8 (2.2)	4.8 (2.5)
Illness burden	10.3 (7.1)	11.0 (7.7)	9.7 (6.3)	9.7 (7.5)
	N (%)			
Males	172 (51.8)	82 (52.2)	81 (50.3)	174 (52.4)
Multimorbidity (2 conditions or +)	315 (94.9)	151 (96.2)	153 (95.0)	313 (94.3)
Multimorbidity (3 conditions or +)	281 (84.6)	132 (84.1)	139 (86.3)	271 (81.6)
Education level				
Incomplete high school	59 (17.8)	20 (12.7)	38 (23.6)	78 (23.5)
High school diploma	110 (33.1)	53 (33.8)	50 (31.1)	122 (36.7)
College	97 (29.2)	47 (29.9)	46 (28.6)	73 (22.0)
University	64 (19.3)	35 (22.3)	27 (16.8)	58 (17.5)
Missing data	2 (0.6)	2 (1.3)	0	1 (0.3)
Household income in CAD$				
< 20,000$	41 (12.3)	19 (12.1)	21 (13.0)	50 (15.1)
20,000$-49,999$	123 (37.0)	53 (33.8)	64 (39.8)	132 (39.8)
50,000$ or +	161 (48.5)	81 (51.6)	73 (45.3)	145 (43.7)
Missing data	7 (2.1)	4 (2.5)	3 (1.9)	5 (1.5)

Marital status				
Married	245 (73.8)	109 (69.4)	127 (78.9)	219 (66.0)
Single or Divorced	71 (21.4)	38 (24.2)	28 (17.4)	98 (29.6)
Widower	16 (4.8)	10 (6.4)	6 (3.7)	15 (4.5)
Employment				
Employed	192 (57.8)	89 (56.7)	91 (56.5)	167 (50.3)
Unemployed	53 (16.0)	22 (14.0)	29 (18.0)	71 (21.4)
Retired	84 (25.3)	44 (28.0)	40 (24.8)	94 (28.3)
Missing data	3 (0.9)	2 (1.3)	1 (0.6)	0

*Excluding patients lost to follow-up (nine in Group A and five in Group C)

Table 2. Self-management scores in Groups A and B at baseline and after 3 months.*

Domain (heiQ)	Group	Baseline		3 months		Baseline vs. 3 months	Group A vs. Group B (3 months)	
		n	Mean (SD)	n	Mean (SD)	Cohen's d (95% CI)	Cohen's d (95% CI)	p*
Health directed behaviour	**A**	162	2.61 (0.73)	153	2.96 (0.63)	0.51 (0.44 to 0.59)	0.27 (0.19 to 0.34)	0.001
	B	163	2.66 (0.78)	156	2.78 (0.72)	0.16 (0.08 to 0.24)		
Positive & active engagement in life	**A**	165	3.10 (0.54)	156	3.24 (0.51)	0.27 (0.21 to 0.23)	0.12 (0.06 to 0.18)	0.319
	B	165	3.10 (0.54)	158	3.18 (0.50)	0.15 (0.10 to 0.21)		
Emotional wellbeing	**A**	160	2.68 (0.64)	149	2.96 (0.60)	0.45 (0.38 to 0.52)	0.19 (0.13 to 0.26)	0.012
	B	160	2.73 (0.63)	153	2.85 (0.56)	0.20 (0.14 to 0.27)		
Self monitoring and insight	**A**	159	3.03 (0.41)	149	3.23 (0.38)	0.51 (0.46 to 0.55)	0.39 (0.34 to 0.44)	0.001

	B	160	3.01 (0.41)	154	3.07 (0.44)	0.14 (0.10 to 0.19)		
Constructive attitudes and approaches	**A**	163	3.07 (0.48)	153	3.22 (0.47)	0.32 (0.27 to 0.37)	0.11 (0.05 to 0.16)	0.048
	B	161	3.13 (0.46)	155	3.17 (0.48)	0.09 (0.03 to 0.14)		
Skill and technique acquisition	**A**	163	2.83 (0.51)	153	3.09 (0.45)	0.54 (0.49 to 0.60)	0.31 (0.26 to 0.36)	0.001
	B	161	2.86 (0.50)	156	2.95 (0.45)	0.19 (0.14 to 0.24)		
Social integration & support	**A**	164	2.98 (0.53)	154	3.09 (0.54)	0.21 (0.15 to 0.27)	0.19 (0.13 to 0.25)	0.098
	B	161	2.95 (0.54)	156	2.99 (0.53)	0.08 (0.02 to 0.13)		
Health service navigation	**A**	165	3.27 (0.41)	154	3.38 (0.42)	0.27 (0.22 to 0.31)	0.35 (0.30 to 0.39)	0.005
	B	166	3.26 (0.42)	160	3.23 (0.45)	-0.07 (-0.12 to -0.02)		

* Mean differences for Cohen's d effect size were calculated as (Mean 3 months - Mean Baseline) and (Mean 3months Group A - Mean 3 months Group B). ANCOVA comparing scores after 3 months, adjusting for baseline.

Table 3. Other variables in Groups A and B at baseline and after 3 months.*

Variable		Group	Baseline		3 months		Baseline vs. 3 months	Group A vs. Group B (3 months)	
			n	Mean (S.D.)	n	Mean (S.D.)	Cohen's d (95% CI)	Cohen's d (95% CI)	p*
HRQoL	Score SEM-CD	A	153	7.5 (1.8)	152	8.0 (1.6)	0.30 (0.10 to 0.49)	0.18 (-0.01 to 0.37)	0.195
		B	160	7.3 (2.0)	158	7.7 (1.7)	0.22 (0.01 to 0.42)		
	PCS	A	155	42.7 (9.7)	155	45.8 (9.3)	0.33 (-0.73 to 1.38)	0.04 (-1.03 to 1.11)	0.017
		B	161	44.6 (10.6)	160	45.4 (10.0)	0.08 (-1.05 to 1.20)		
	MCS	A	155	46.7 (10.7)	155	49.8 (9.9)	0.30 (-0.83 to 1.44)	0.04 (-1.02 to 1.10)	0.159
		B	161	47.9 (10.8)	160	49.4 (9.4)	0.15 (-0.96 to 1.25)		
	SF-6D	A	154	0.683 (0.131)	153	0.729 (0.134)	0.35 (0.33 to 0.36)	0.00 (-0.01 to 0.01)	0.041

	B	160	0.715 (0.129)	159	0.729 (0.126)	0.11 (0.10 to 0.12)		
BMI (Kg/m^2)	A	152	32.0 (7.2)	148	31.5 (7.4)	-0.06 (-0.89 to 0.75)	0.04 (-0.75 to 0.84)	0.900
	B	155	31.2 (7.0)	157	31.2 (6.8)	0.00 (-0.76 to 0.76)		

*Mean differences for Cohen's d effect size were calculated as (Mean 3 months - Mean Baseline) and (Mean 3months Group A - Mean 3 months Group B). ANCOVA comparing scores after 3 months, adjusting for baseline.

SEM-CD = Self-Efficacy for Managing Chronic Disease; HRQoL = Health Related Quality of Life; PCS = Physical Component Summary of SF-12; MCS = Mental Component Summary of SF-12; SF-6D = Single index of SF-12; BMI = Body Mass Index.

Table 4. Results of logistic regression analysis for categorical variables at 3 months adjusted for their baseline values.

Variable	Group	Baseline n (%)	3 months n (%)	Adjusted Odds ratio	95% CI*
DP	Group A	16 (10.4)	8 (5.2)	0.84	0.29 to 2.45
	Group B	15 (9.3)	9 (5.7)		
F & V	Group A	49 (31.6)	83 (55.0)	2.36	1.41 to 3.95
	Group B	50 (31.1)	61 (38.1)		
PA	Group A	15 (9.7)	32 (20.8)	3.81	1.65 to 8.76
	Group B	22 (13.7)	18 (11.3)		

* DP = Presence of psychological distress; F&V = Recommended fruit and vegetable; PA = Recommended physical activity; 95% CI = 95% Confidence Interval.

Table 5. Results of the before-and-after design in participants of Group A.*

Variable (n)*	Baseline	3 months	12 months	Baseline vs. 3 months		Baseline vs. 12 months	
		Mean (SD)		Cohen's d (95% CI)	p	Cohen's d (95% CI)	p
Health directed behaviour (140)	2.62 (0.75)	2.96 (0.64)	2.93 (0.64)	0.49 (0.41 to 0.57)	<0.001	0.45 (0.37 to 0.53)	<0.001
Positive & active engagement in life (142)	3.12 (0.53)	3.25 (0.51)	3.29 (0.49)	0.25 (0.19 to 0.31)	<0.001	0.33 (0.28 to 0.39)	<0.001
Emotional well-being (138)	2.69 (0.65)	2.95 (0.60)	2.98 (0.64)	0.42 (0.34 to 0.49)	<0.001	0.45 (0.38 to 0.53)	<0.001
Self-monitoring and insight (137)	3.06 (0.41)	3.24 (0.37)	3.26 (0.37)	0.46 (0.42 to 0.51)	<0.001	0.51 (0.47 to 0.56)	<0.001
Constructive	3.09 (0.47)	3.24 (0.46)	3.27 (0.47)	0.32 (0.27 to 0.38)	<0.001	0.38 (0.33 to 0.44)	<0.001

attitudes and approaches (142)							
Skill and technique acquisition (141)	2.85 (0.50)	3.09 (0.43)	3.12 (0.48)	0.52 (0.46 to 0.57)	<0.001	0.55 (0.50 to 0.61)	<0.001
Social integration and support (142)	2.98 (0.54)	3.09 (0.54)	3.13(0.56)	0.20 (0.14 to 0.27)	0.003	0.27 (0.21 to 0.34)	<0.001
Health service navigation (143)	3.28 (0.41)	3.39 (0.42)	3.35 (0.44)	0.27 (0.22 to 0.31)	0.006	0.17 (0.11 to 0.21)	0.104
Score SEM-CD (136)	7.41 (1.82)	7.94 (1.57)	7.76 (1.94)	0.31 (0.11 to 0.51)	<0.001	0.19 (-0.04 to 0.41)	0.025
PCS (143)	42.4 (9.8)	45.8 (9.3)	46.7 (9.8)	0.36 (-0.75 to 1.46)	<0.001	0.44 (-0.69 to 1.57)	<0.001

MCS (143)	46.8 (10.9)	49.5 (10.1)	49.4 (10.2)	0.26 (-0.96 to 1.47)	<0.001	0.25 (-0.97 to 1.47)	0.002
SF-6D (140)	0.661 (0.108)	0.698 (0.113)	0.704 (0.106)	0.34 (0.32 to 0.35)	<0.001	0.40 (0.39 to 0.42)	<0.001
BMI (132)	31.6 (6.7)	31.3 (7.5)	30.6 (6.8)	-0.04 (-0.90 to 0.81)	0.531	-0.15 (-0.96 to 0.66)	<0.001

	n (%)			**Relative Risk * (95 % CI)**	**p**	**Relative Risk (95% CI)**	**p**
PD (140)	15 (10.7)	8 (5.7)	12 (8.6)	0.53 (0.23 to 1.22)	0.092	0.80 (0.39 to 1.65)	0.581
F & V (140)	48 (34.3)	79 (56.4)	70 (50.0)	1.65 (1.25 to 2.16)	<0.001	1.46 (1.10 to 1.94)	<0.001
PA (143)	14 (9.8)	30 (21.0)	23 (16.1)	2.14 (1.19 to 3.87)	0.002	1.64 (0.88 to 3.06)	0.093

* Student's paired t-test for continuous variables, and McNemar's test for categorical variables (calculated only for subjects with data at the three measuring times). Baseline was the reference category in Relative Risk calculation.

Mean difference for Cohen's d effect size was calculated as (Mean 3months - Mean Baseline) and (Mean 12 months - Baseline).

SEM-CD = Self-Efficacy for Managing Chronic Disease; PCS = Physical Component Summary of SF-12; MCS = Mental Component Summary of SF-12; SF-6D = Single index of SF-12; BMI = Body Mass Index (Kg/m^2); DP = Presence of psychological distress; F&V = Recommended fruit and vegetables; PA = Recommended physical activity.

Table 6. Comparison at one year in the quasi-experimental design.

Variable*	Groups A and B		Group C		Groups A and B vs. Group C at 12 months	
	Baseline	12 months	Baseline	12 months		
	Mean (SD)		Mean (SD)		Cohen's d (95% CI)	p**
PCS	43.6 (10.3)	45.6 (9.7)	43.6 (11.7)	43.8 (11.3)	0.17 (-0.63 to 0.97)	0.011
MCS	47.1 (10.8)	49.6 (9.6)	47.2 (10.6)	48.9 (10.3)	0.07 (-0.69 to 0.83)	0.258
BMI	31.8 (7.2)	30.7 (7.0)	30.6 (6.1)	30.6 (6.3)	0.02 (-0.49 to 0.52)	<0.001
	n (%)		n (%)		Odds ratio (95% CI)	p
PD	34(10.3)	17(5.4)	40(12.0)	31(9.4)	1.03 (0.59 to 1.80)	0.103
F & V	103(31.0)	127(45.4)	147(45.2)	177(56.0)	1.31 (0.90 to 1.90)	0.155
PA	39(11.8)	49(17.5)	60(18.2)	56(17.1)	0.77 (0.48 to 1.23)	0.266

* PCS = Physical Component Summary of SF-12; MCS = Mental Component Summary of SF-12; BMI = Body Mass Index (Kg/m^2);

DP = Presence of psychological distress; F&V = Recommended fruit and vegetables; PA = Recommended physical activity.

** ANCOVA (continuous variables) or logistic regression (dichotomous variables), adjusting for scores at baseline, age and sex

Figure legends

Figure 1. Flow diagram of PR1MAC study.

Figure 2. Relative risk (RR) and 95% confidence interval (95% CI) of a reliable improvement from baseline at 3 months in Group A (Group B as reference category) for each domain of self-management.

Figure 3. Distribution of changes in Group A from baseline over a year in self-management domains. Numbers inside the bars show absolute numbers of patients.

Figure 1

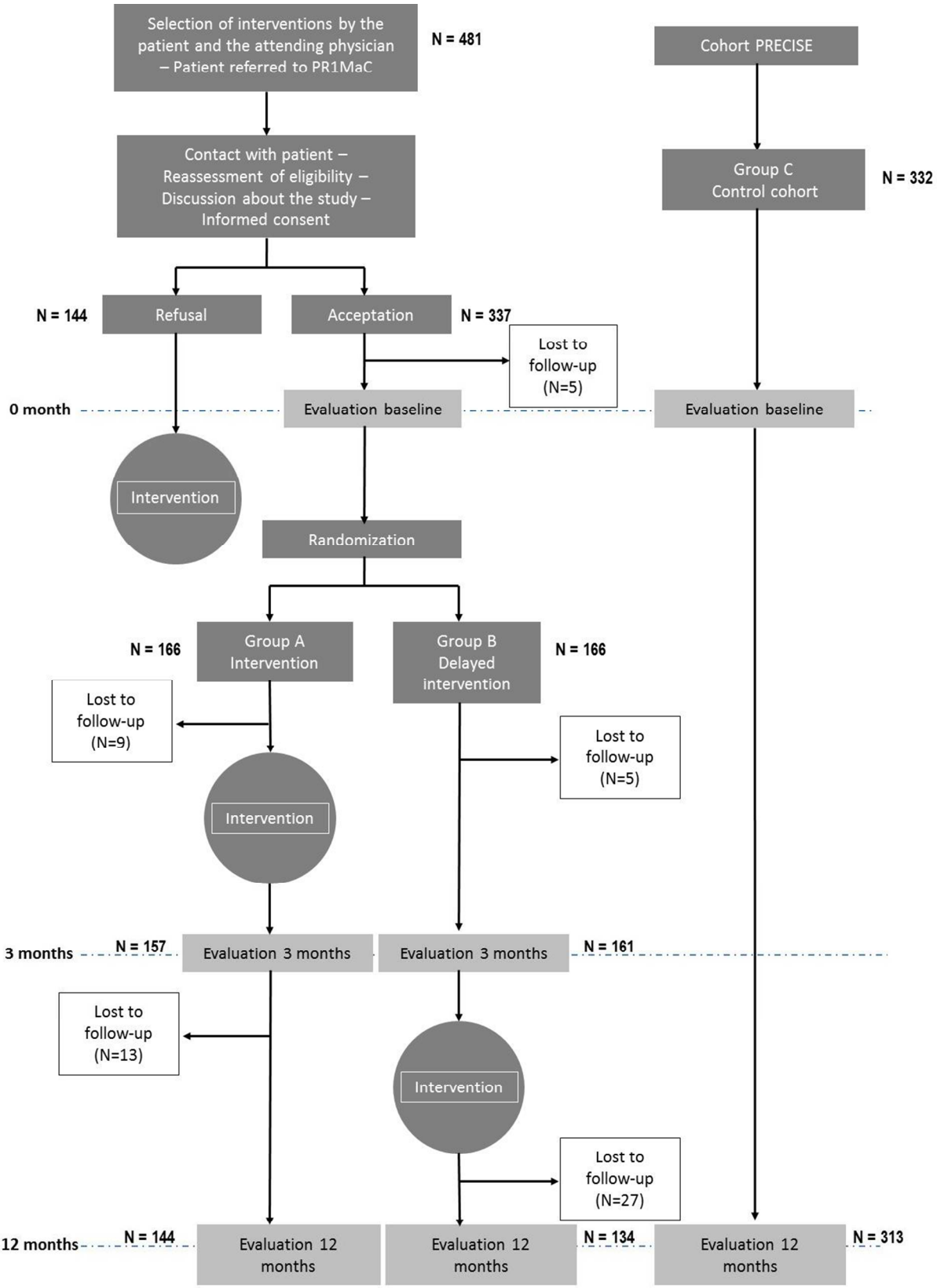

Figure 2

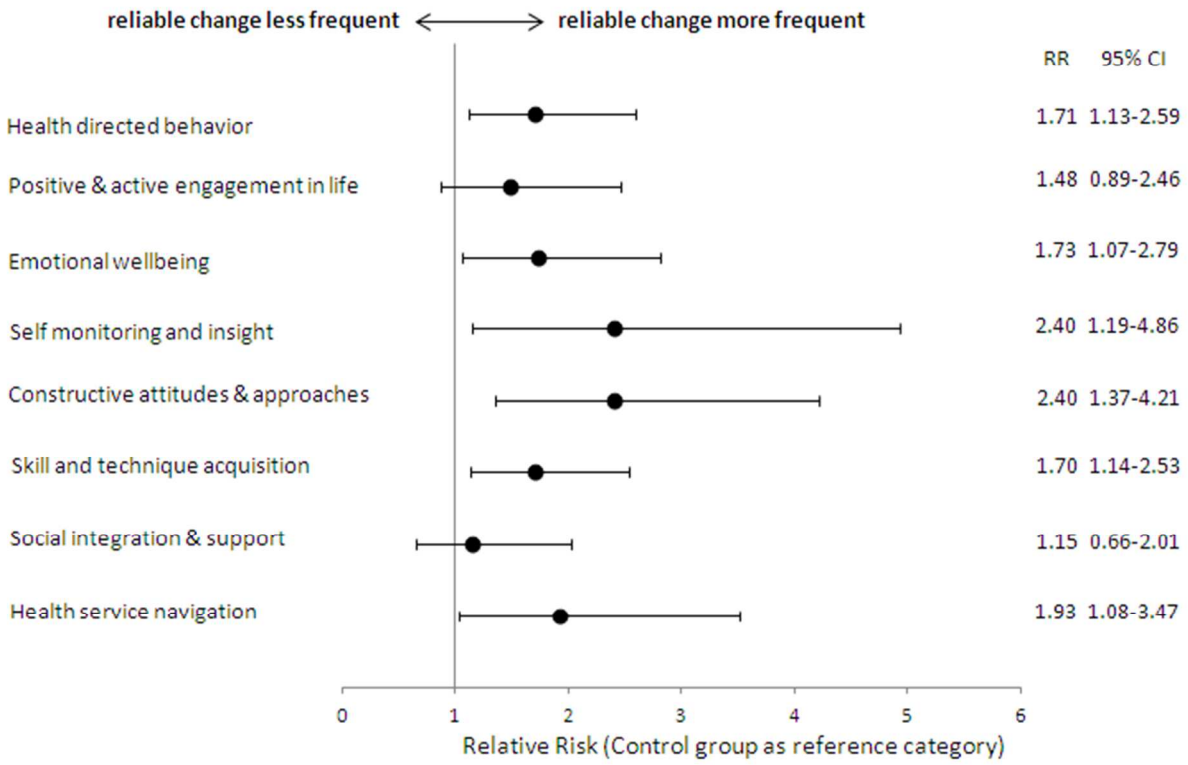

Figure 3