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Patient-Centred Innovation for Multimorbidity Care: Mixed-methods, Randomized Trial and Qualitative Study of the Patients' Experience

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Abstract

Background: Patient-centered interventions to help patients with multimorbidity have had mixed results.

Aim: Assess the effectiveness of a provider-created patient-centred multi-provider case conference with follow-up; understand under what circumstances it worked.

Design and Setting: Mixed-methods design with a pragmatic randomized trial and qualitative study, 9 primary care sites, Ontario, Canada.

Method: Patients, 18 to 80 years with three plus chronic conditions, were referred to the Telemedicine IMPACT Plus intervention; a nurse and patient planned a multi-provider case conference creating a care plan. The patients were randomized into intervention or control group. Two subgroup analyses and a fidelity assessment were conducted. Primary outcomes, at four months, were: Self-management; Self-efficacy. Secondary outcomes were: Mental and Physical Health status; Quality of life; Health behaviors. A thematic analysis explored the patients' experiences of the intervention.

Results: 86 patients in the intervention group and 77 in the control group showed no differences except the intervention was effective for mental health status in the subgroup having an income of equal to or greater than $50K CAD (Beta

Coefficient=11.003, p=0.006). More providers and follow-up hours were associated with poorer outcomes. Five qualitative themes were: valuing the team; feeling supported; receiving a follow-up plan; being offered new and helpful additions to their treatment regimen; and experiencing positive outcomes. Conclusions: There was no effect of the intervention overall, except for the patients with $50K CAD or greater income, implying a need to address the costs of uncovered intervention components. Findings suggest a need to optimize team composition and follow-up.

How this fits in

Patient-centred interventions for patients with multimorbidity have shown mixed results to date, so we seek information to help improve such interventions. The present study indicated neutral impact on primary outcomes. Given the subgroup results, the qualitative findings and the fidelity assessment, policy-makers and clinicians are encouraged to seek ways to enhance care for patients with incomes of less than $50K CAD; to optimize team composition based on individual patient's goals and abilities; and to enhance and tailor follow-up care.

INTRODUCTION

Multimorbidity is common, in younger ages than previously imagined and especially for low income groups (1,2,3). There is a growing international agreement for solutions to be in primary care settings and in a patient-centred way (4,5). However, patient-centred interventions for patients with multimorbidity vary greatly, typically including both principles of partnership between the patient and health professional (6,7) but also aspects of system integration (8) as well as some technologies (9). Evidence of effectiveness is inconsistent (8,10-12), including six recent trials (13-18). It is becoming clear that

we should proceed to improve the interventions (19) Testing the interventions but also illuminating mechanisms of success and failure, may assist in such improvements (19). Therefore, this paper has two research goals: 1) to assess the effectiveness of a flexible patient-centred innovation (which arose from real-world practice in the policy context of Ontario Canada) in relation to relevant patient-reported outcomes; and 2) to ascertain the contexts and under what circumstances the innovation worked for patients or not. A concurrent triangulation mixed-methods study (20) was mounted with two simultaneous components: a pragmatic (21,22) trial for goal 1; and a qualitative study of patients' experience of the intervention for goal 2.

METHODS OF THE TRIAL:

Participants Eligibility: Patients who were: literate; 18-80 years old; had never before received the intervention; and, in the family physician's clinical judgement, were cognitively intact and had three or more chronic conditions (23, 24). Eighty years was chosen to minimize loss to follow-up because of admission to an institution. Three or more chronic conditions was chosen for two reasons: they engender more burden for the patient and the family physician than the other common definition of multimorbidity of two or more conditions; and the patients

had more medical needs so they had the potential for improvement in outcomes. The number of chronic conditions was validated with the patient's self report in the baseline questionnaire.

Design and Setting: A pragmatic randomized trial was conducted. Nine team-based family practices familiar with the intervention (and solo practices and emergency departments affiliated with those teams) in Toronto, Ontario, Canada where the provincial policy context emphasized innovations for complex patients with high health care utilization. Ethics approval was received for this mixed-methods study from the Health Sciences Research Ethics Board of Western University (106921). The protocol has been published (25). The trial was registered in Ontario Canada NCTO2742597. The CONSORT guidelines for pragmatic trials were followed for reporting methods and results (26).

Intervention Development: The Telemedicine IMPACT Plus (TIP) program a patient-centred multi-provider case conference was developed by the providers and then chosen by the researchers from among six identified programs in a province-wide environmental scan. It was chosen because of its lengthy development and preliminary evaluation. The program was developed in a way that aligned with guidelines for complex interventions (27-29), covering theory,

gaps, pre-trial evaluations and adaptation over time. The TIP program contained two key theoretical underpinnings: 1) patient-centred process in the patient-provider interaction (6); and 2) an integrated version of the Chronic Care Model (30) Two evidence gaps from a scoping review conducted by the team (31) were: lack of empowering patient-centred communication; and lack of integrated care among multiple providers in the context of multimorbidity care. Pre-trial evaluations of early versions of the intervention revealed enablers and barriers of patient and provider enthusiasm in terms of: 1) time and scheduling of the multiple providers; 2) patient need for support to implement recommendations (32); 3) patient-centred agenda setting; 4) the process to identify and invite the patient; and 5) remuneration of providers (33). Over a period of ten years, the intervention was shortened, it provided a telemedicine (video) option as well as the face-to-face option, and remuneration was negotiated. The patient-centred invitation to the patient to engage in the discussion was honed “What are your goals for this session?" in the context of improved agenda setting.

Description of the intervention: The nurse, hired by the program, met with each patient to understand what mattered to him/her, and then planned and coordinated a case-conference of approximately six providers relevant to that patient: family physician (known to the patient); internist; psychiatrist; social

worker; physiotherapist; occupational therapist; pharmacist; dietician; and home care case manager. In preparation, the nurse accessed the patient's file from the family physician and forwarded all relevant results, medical and social history, to the intervention team. The providers met (face-to-face or by video) with the patient for 1 to 1.5 hours for a mutual collaboration focusing on patient goals resulting in an agreed-upon plan. Follow-up was provided by the nurse to help execute the recommendations over the next four months. A full description is shown in Box S1 using the TIDieR Checklist (34).

The intervention and the literature: The intervention aligned with those in the literature in which three main types are described: patient-oriented, organizational and training interventions. Combining 47 trials in two reviews (8,35), we found patient-oriented interventions were tested in 36% of trials; organizational in 51% (of which all had a patient-oriented component as well); and training in 13% (not an element of our intervention). The focus on patient goals was a common thread in all the patient-oriented interventions; however, TIP's multi-provider team was unique and not found in any of the 47 interventions, the closest being a team of the practice nurse, psychologist and psychiatrist (36).

Pilot evaluation of the intervention: A pilot study to determine the feasibility of suggested outcomes was conducted to estimate recruitment and identify effect sizes for sample size calculation (37).

Description of Usual care: Control group patients received usual care in the office of their FP (typically a 15-minute visit) plus a one-page list of community resources that patients may contact if they wish. Three quarters of the patients were referred by FPs who had access to an interprofessional team on-site and one quarter did not. The three quarters worked in the province of Ontario's model of team based care called the Family Health Team so that a nurse practitioner and social worker would be readily available on-site. The other quarter of patients were referred by FPs who were in non-team practice but who could refer patients to medical specialists and health professionals off-site.

Recruitment: Nine team-based practices and their affiliated practitioners referred eligible patients. There was a two-step recruitment process. The clinician approached patients selected based on clinical judgement and asked consent to send their name to the researchers. The Project Coordinator received names of patients and contacted them to explain the project in detail and obtain signed consent to participate.

Outcomes: Assessed at baseline and 4 months after the case conference, a period long enough for the nurse and patient to complete the plan and feasible for follow-up. There were two primary outcomes chosen to represent patient education, empowerment and agency: Health Education Impact Questionnaire (HeiQ,38); and the Self-Efficacy for Managing Chronic Disease scale (SEM,39). There were four secondary outcomes: VR12 Health Survey, Physical and Mental Health Status (40); Quality of Life (41); Kessler Psychological Distress Scale (42); and Health Behaviour Survey (43). Psychometric properties are available in the protocol paper for the project (25).

Sample size: For the 2 primary outcomes (HeiQ and SEM) comparing mean scores to detect a medium effect size (0.5) with a 2-sided alpha= 0.05 and 80% power, 64 participants were needed in intervention group and the same number in the control group, n=128 (44). Allowing a 15% drop-out, we aimed to recruit 150 patients, 75 in each group.

Randomization: Individual patients were randomly allocated. Box S2 details the procedures using the CONSORT guidelines (26) regarding: assignment of the

intervention; sequence generation; allocation concealment; implementation; blinding; and data collection.

Statistical Methods: Outcome data were analyzed using the mixed models for repeated measures (MMRM, 45). This method is a simple form of mixed effect without explicitly modeling the random effects, but rather explicitly modeling correlations among measurements within a subject. An advantage is it can effectively handle missing data without strong assumptions of missing completely at random. It also controlled for the baseline outcome measure. Nonetheless, a sensitivity analysis omitting the lost cases was conducted. In addition, two exploratory post-hoc subgroup analyses were conducted on: 1) less than $50K income versus greater than or equal to $50K income (the sample's median income); and 2) greater than or equal to 6 morbidities versus lower (using MMRM again). Also, the relationship between the fidelity of the intervention (on a subset of 40 intervention patients) and outcomes was analyzed using ANCOVA controlling for baseline.

METHODS OF THE QUALITATIVE STUDY OF PATIENTS' EXPERIENCE OF THE INTERVENTION

Design: A thematic analysis was used to explore the patients' experiences of context, process and under what circumstances the intervention worked or failed to work (46). It occurred at the same time as the trial measures were being collected.

Participant Recruitment and Final Sample: Participants were selected purposively from the trial intervention arm participants. A maximum variation sample varied by age, sex, and practice. Participants were interviewed four months after their TIP case conference at a time and date organized by the study Research Coordinator. The interviewers had no prior relationship with participants. Before the interview, participants read a letter of information which outlined the reasons for the research and informed consent was obtained

Data Collection: Semi-structured individual interviews of 30-60 minutes, conducted with each participant alone in their home or family physicians' office (See the guide in Box S3), were audio-recorded and transcribed verbatim. Four members of the research team (3 females and 1 male) trained in qualitative interviews, conducted the qualitative data collection and analysis (JBB, SR, PB and the Research Assistant) but were not involved in the trial data collection.

Data Analysis: The data analysis was both iterative and interpretive. First, all transcripts were independently reviewed and coded by the four researchers to

determine the key concepts emerging from the data. The researchers then met shared and created a consensus that informed the development of the coding template. This process continued until no new themes were identified; the data were input into NVivo. In the final step, the research team identified overarching themes and exemplar quotes for each theme. The trustworthiness and credibility was ensured by using audio-recording and verbatim transcripts, independent and team analysis, and field notes following each interview. A commitment to reflexivity considered how the researchers' professional backgrounds (e.g., social work, epidemiology, family medicine), particularly during the coding and interpretation of the data, could influence the findings.

TRIAL RESULTS

Participants

Figure 1 shows the flow diagram of recruitment of patients. The sample attained was 86 for the intervention group and 77 for the control group. This sample differed from the general Ontario population (47), being older, more female, better educated and having higher income.

Baseline (T1) patient characteristics are shown in Table 3. As expected due to randomization, there were no significant differences.

Outcomes and estimates

Table 4 shows the intent to treat comparison of the intervention and control groups on primary outcomes at four months (T2) with no significant differences revealed. Table 5 shows similar lack of difference on the secondary outcomes. Tables 4 and 5 show modest improvements from T1 to T2 in both groups.

Ancillary analyses

Subgroup analyses showed no difference in the effect of the intervention for patients with 6 or more chronic conditions versus less than 6; however, as shown in Figure 2, the intervention was effective for patients with incomes at or above $50K CAD for the outcome of Mental Health Status (Beta Coefficient=11.003, p=0.006). Exploratory analyses regarding the fidelity of the intervention revealed that: a) having 3+ hours (versus fewer hours) of nurse follow-up work after the intervention was related to significantly less improvement in primary outcomes from T1 to T2; and b) having $\geq$ 6 healthcare providers involved in the intervention (versus < 6 providers) was related to less improvement.

QUALITATIVE FINDINGS

The final sample consisted of 14 patients (male [6], female [8]) who ranged in age from 33-80 years. Five themes reflected the patients' experience of the intervention: valuing the team experience; feeling supported in meeting their goals; receiving advice and a follow-up plan; being offered new and helpful additions to their treatment regimen; and experiencing positive outcomes.

The first theme included how all players shared the same information and had buy-in to the recommended plans.

> "The nurse got together a dietitian, my family doctor, a social worker, a psychiatrist, a pharmacist – a whole bunch of people together…We had a video here [at my home], a conversation and just so everybody was on the same page with what I was doing. It was really good. "(#4-F).

As well, the diversity of team members meant connections to a lot of programs which were found helpful: *"Because I have various health issues, this gave me some kind of all-in-one resource!!* (#11-M). However, a downside was that the

new services could be exhausting: *"I had so many appointments after [the consultation], it was tiring!!"* (#4-F).

The second theme was how the participants felt supported in meeting their goals.

> "I felt that they truly were committed to the interview and looking to see if they could help me to reach my goals…. It was often they'd have a perspective and then I'd respond to that as well. Or they'd ask me how I felt about that." (#8-F).

Patients' goals were explicitly elicited "*I was asked, 'What do you want from this?' So I said, 'I would like to be able to walk a mile… I am not asking to run a marathon, just a mile without pain.'* (#7-M). Patients felt validated. *"Well they heard me…they validated me. So that wasn't happening [(before)]*." (#4-F).

The third theme was advice and follow-up. The advice was considered plentiful, new and helpful and, in some instances, the best part of the program.

> "I felt really good coming out of that. That was some of the best answers I felt like I'd received up to that point... I came out of it with kind of a list of ideas of different things to try to help improve my condition. (#1-M).

With regard to follow-up: *"The nurse came back [to the patient's home] a week after that with a synopsis of everything that was written down and reviewed everything, not word for word, but the highlights, a summary of everything."* (#7-M).

In contrast, when presented with only verbal instructions or a list that was not coalesced into a plan, they were left with little guidance at the conclusion of the consultation:

> "It has been frustrating not to have a little bit more guidance about how to take the individual suggestions and put those into an actual plan… The list I was given seemed to be in the order they thought of them and not really further processed into an actual treatment plan with step by step priorities." (#12-F)

The fourth theme was being offered new and helpful additions to their treatment regimen. "*Clear solutions yeah….a walker…. medication…. eating….that pleases me very much….".* (#12-F). *"As a result of this intervention, the social worker*

arranged for me to get a walker. So I go out for walks now which I hadn't been doing for the longest time. I find it very liberating." (#5-M).

Also psychotherapy and physiotherapy were repeatedly mentioned as helpful additions to their treatment regime. *"The psychotherapist is a good match for me and positive work is being done. I am over the moon optimistic."* (#13-F). *"I feel like the physiotherapist has been helping. Yeah, anything that gets your strength back is wonderful…. Especially muscles, because you can get them back, and I didn't know how to do it."* (#12-F).

The fifth theme was the participants' descriptions of the health improvements, attributed to the program, which reflected two dimensions: improved functional ability; and a new positive and hopeful attitude. For some, increased function was due to a decrease in pain. *"I'm feeling better. I don't have the horrible pain that I had before…I feel that I have the ability to do things now that a few months ago I wouldn't think of doing."* (#5-M). "*So I have had some improvement in being able to do things around the house."* (#12-F). Improved functional ability appeared linked to a sense of hope: *"There are things that I'm looking forward to, which*

before the intervention I wasn't." (#5-M). "*Without it, I would be sitting here miserable…there would have been no hope".* (#3-F).

DISCUSSION

Summary of main findings

The trial found no significant intervention effects on primary outcomes; one subgroup (at or above an income of $50K) significantly benefitted in terms of the mental health outcome; and qualitative and fidelity findings suggest improvements to the intervention.

Strengths and Limitations

This intervention was developed by providers and pre-tested before the trial; it used a mixed-methods design to explore patient experience in addition to the effects on validated patient-reported outcome measures. Susceptibility bias was avoided by using envelopes in random sequence; detection and follow-up bias by using sealed and opaque envelopes and having a different staff person administer patient questionnaires.

Several limitations were: a relatively small sample size by comparison to other recent trials although meeting the estimated sample size which was n=128; and

an unrepresentative sample (being older, more female and higher social status). Health care utilization outcomes with their associated cost implications will be handled in separate analyses which are underway. Future studies may want to include a process evaluation involving patients plus providers and decision-makers.

Comparison with the literature

The current study advances on previous work by testing an intervention enhancing everyday practice. This intervention should overcome the problem of implementation lapses found in other studies (19) because it was provider-created which goes even further than a co-created intervention (15). Most interventions studied to date enhance the organization of care (8,31), whereas ours includes an explicit patient-centred component. The mixed-methods design provides suggestions for improving the intervention as well as insights on how, and for whom, it works or fails to work (19), which is important in the face of neutral or mixed results in recent systematic reviews (8,10-12) and six recent trials (13-18). The lack of impact on outcomes for patients with less than $50K CAD income, contrasts with Mercer et al.'s (15) intervention which did work for socioeconomically deprived patients; they focused on self-management support, more time and continuity of care, aspects of care that could enhance our

intervention follow-up. Finally, the present study aligns with those which did find impacts on mental health outcomes (8).

Implications

We offer three possible explanations for the neutral results in the pragmatic trial. First, both the control group and the intervention group seemed to improve by small amounts from T1 to T2. We note that three quarters of control group patients experienced usual care within an Ontario-wide enhanced primary care team model whose standard of care may already have been high. Nonetheless, the control patients did not receive the case-conference. Second, lack of alignment of the outcome measures with intervention goals and patient expectations may be a problem (48). Our trial found impact on the mental health outcome for a subgroup of patients and our qualitative findings focused on patients' functional goals as well as patients feeling validated, liberated, optimistic and hopeful; potential useful outcomes for future research. Third, while there were no indications of implementation failure (19) with this provider-created intervention, lack of fidelity to some components may have compromised impact.

Two such modifiable components were highlighted by the qualitative findings and the fidelity assessment. Six or more providers in the case conference was linked to negative outcomes, suggesting that the ideal/optimal team composition may need to be tailored to patient preferences Tailoring has been suggested by others (18) The number of nurse hours during the follow-up and how these hours are used, may need rethinking, perhaps increasing the involvement of the family physician and the multidisciplinary team in the follow-up and emulating Mercer et al's (15) intervention's emphasis on continuity of care and self-management support. Both of these findings about the number of providers and nursing hours imply a level of complexity that led to confusion; one solution to that may be specifically coalescing the plan into written actionable steps.

Secondly, patients qualitatively experienced promising impacts of the very recommendations that required extra outlay of costs, i.e., that were not covered by Ontario Canada's universal health care system, such as physiotherapy and psychotherapy, suggesting policy implications. Tied with this, the finding that patients with incomes at or above $50K CAD did benefit from the intervention, is worth considering seriously. In Toronto Canada, $50K income or above represents about 36% of people (49), so the intervention was not just effective for a small percentage of very high income patients, but for a range of high to middle income

patients. Cognitive load due to the complexity of the recommendations and costs likely played a role in the lack of impact of the intervention for patients with incomes less than $50K CAD. Equity in patient-centred multimorbidity care may become an increasingly compelling issue in healthcare delivery.

Summary of the Implications for Practice and Research

In practice, the intervention could be improved by optimizing team composition to individual patient preferences, and by reducing the complexities for the patient through a clear care plan with actionable steps. For the deprived subgroup of patients, additional supports will be needed. In research, provider-created interventions can be sought to avoid implementation failures; mental health outcomes, functional goals and validation may be the outcomes of choice; and a process evaluation may enhance a mixed-method study of an intervention.

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FIGURE 1: Flow Chart of Patients

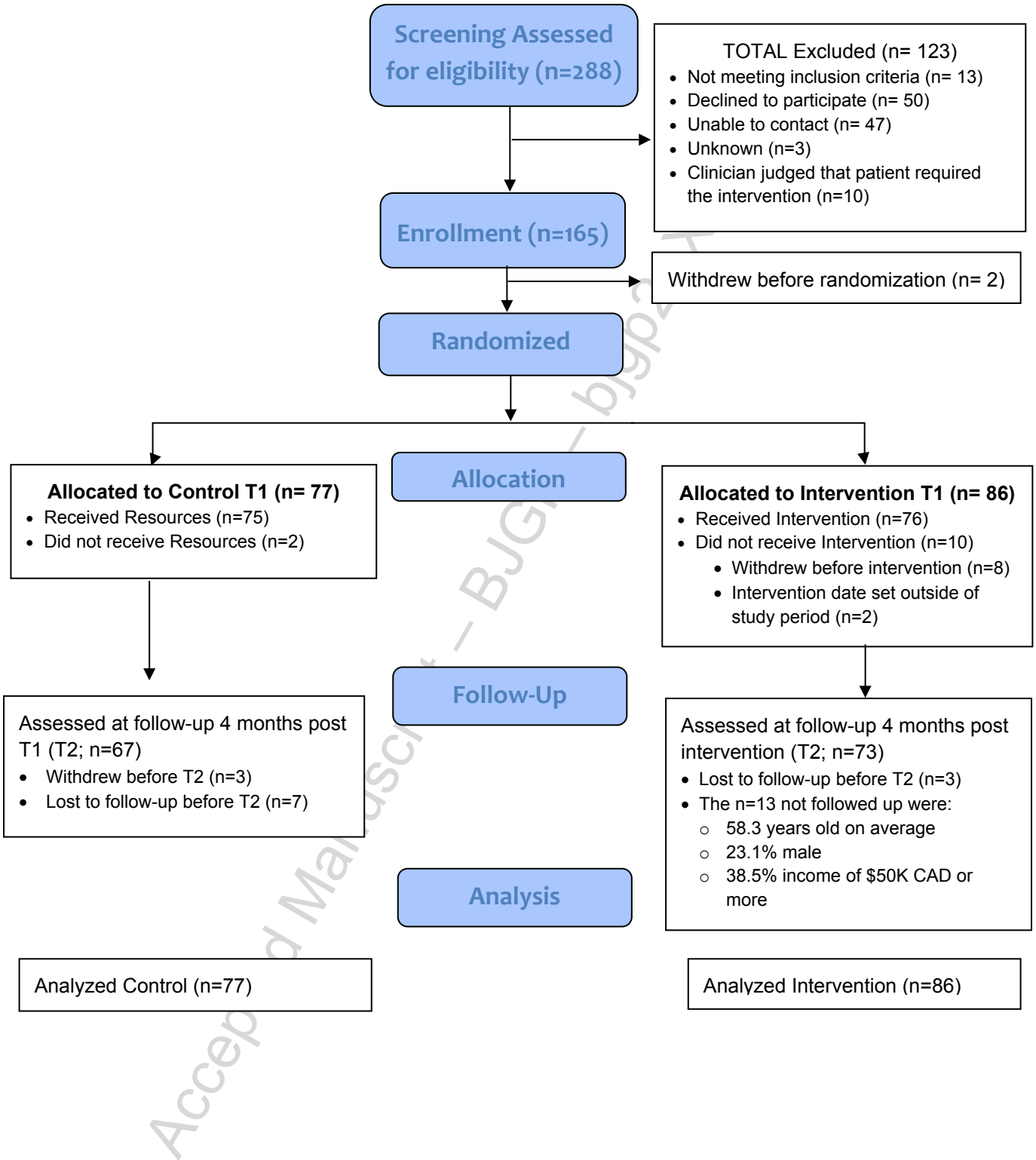
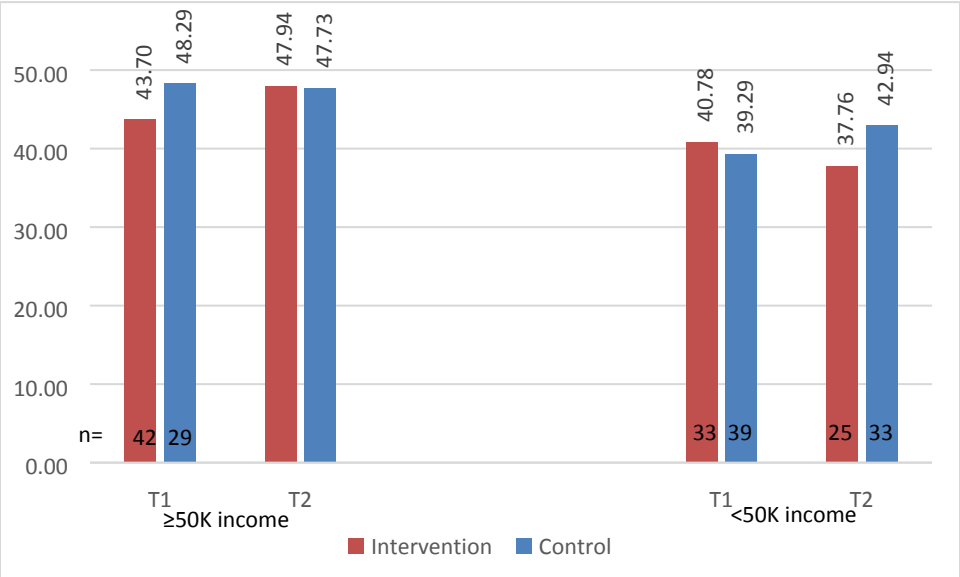


Figure 2: Intervention and Control Group in Relation to Mental Health Status by Income Subgroups*



*Mean values of Mental Health Status in a significant 3 way interaction between Treatment by Time by Income in an analysis by Mixed-effects Repeated Measures using STATA v 13 (Beta Coefficient=11.003, p=0.006)

Table 1: Patient Characteristics

	Intervention n = 86	Control n = 77	
	Mean (SD)		p
AGE (YR.)	61.9 (13.9)	63.1 (13.9)	0.941
CHRONIC CONDITIONS			
# of conditions per participant	6.1 (2.5)	5.9 (2.3)	0.414
		N (%)	p
Arthritis or rheumatoid arthritis	51 (59.3)	45 (58.4)	0.936
Depression or Anxiety	49 (57.0)	40 (51.9)	0.497
Hypertension	47 (54.7)	40 (51.9)	0.253
Chronic Musculoskeletal	46 (53.5)	29 (37.7)	0.027
Stomach Problems	42 (48.8)	36 (46.8)	0.518
Colon Problems	35 (40.7)	24 (31.2)	0.167
Hyperlipidemia	33 (38.4)	29 (37.7)	0.412
Asthma, COPD	32 (37.2)	29 (37.7)	0.644
Cardiovascular Disease	31 (36.0)	35 (45.5)	0.595
Diabetes	30 (34.9)	28 (36.4)	0.861
Thyroid Disorder	22 (25.6)	17 (22.1)	0.566
Osteoporosis	20 (23.3)	20 (26.0)	0.773
Chronic Urinary Problem	13 (15.1)	13 (16.9)	0.955
Stroke or TIA	13 (15.1)	9 (11.7)	0.390
Heart Failure (valve problem or replacement)	12 (14.0)	12 (15.6)	0.913
Cancer in previous 5 years	10 (11.6)	12 (15.6)	0.668
Kidney Disease or Failure	9 (10.5)	7 (9.1)	0.616
	N (%)		p
GENDER (Male)	29 (34.1)	27 (35.1)	0.632
EDUCATION LEVEL			0.755

Incomplete secondary school	10 (11.8)	8 (10.4)	
Completed secondary school	9 (10.6)	11 (14.3)	
Some University or completed College	26 (30.6)	27 (35.1)	
University (undergraduate or above completed)	40 (47.1)	31 (40.3)	
HOUSEHOLD INCOME IN CAD$			
< $20,000	20(23.5)	17 (22.1)	
$20,000-$49,999	13 (15.3)	22 (28.6)	0.203
$50,000 or +	42 (49.4)	29 (37.7)	
Missing data	11(11.8)	9(11.7)	
MARITAL STATUS			
Married	37 (43.5)	37 (48.1)	
Separated or Divorced	17 (20.0)	15 (19.5)	0.494
Widower	8 (9.4)	11 (14.3)	
Never Married	23 (27.1)	14 (18.2)	
EMPLOYMENT			
Employed	17 (20.0)	14 (18.4)	
Unemployed	31 (36.5)	28 (36.8)	0.967
Retired	37 (43.5)	34 (44.7)	

* HIV and chronic hepatitis not included as cell counts were less than 5, in spite of their inclusion in the list of chronic conditions (22).

Table 2 Intention to treat analyses of Primary Outcomes at four month follow-up in study of Telemedicine IMPACT Plus for patients with multimorbidity

	Intervention*		Control		Beta Coefficient (95% CI)**	P Value
Primary Outcomes	T1 (n=86)	T2 (n=73)	T1 (n=77)	T2 (n=67)		
HeiQ Outcomes (Range 1=low to 4=high)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Health directed behaviour	2.72 (0.748)	2.86 (0.586)	2.83 (0.725)	2.93 (0.579)	0.049 (-0.149 to 0.247)	0.626
Positive, Active, Engaged Life	2.90 (0.617)	2.93 (0.531)	2.84 (0.587)	2.95 (0.506)	-0.067 (-0.231 to 0.098)	0.429
Emotional wellbeing	2.42 (0.744)	2.56 (0.581)	2.45 (0.712)	2.61 (0.592)	-0.018 (-0.189 to 0.153)	0.836
Self-monitoring and insight	3.07 (0.372)	3.10 (0.277)	3.13 (0.355)	3.14 (0.305)	0.024 (-0.090 to 0.138)	0.681
Constructive attitudes and approaches	2.90 (0.644)	2.88 (0.464)	2.87 (0.572)	2.96 (0.526)	-0.108 (-0.264 to 0.048)	0.174
Skill and technique acquisition	2.75 (0.512)	2.83 (0.366)	2.76 (0.430)	2.94 (0.420)	-0.082 (-0.219 to 0.055)	0.243
Social integration and support	2.80 (0.679)	2.85 (0.499)	2.68 (0.647)	2.87 (0.524)	-0.152 (-0.309 to 0.005)	0.057
Health services navigation	3.13	3.11	3.11	3.17	-0.064	0.381

	(0.482)	(0.408)	(0.475)	(0.455)	(-0.207 to 0.079)	
Self-efficacy (semcdscore Range 1=low to 10=high)	5.69 (2.269)	5.93 (2.057)	5.59 (2.199)	6.06 (2.114)	-0.184 (-0.831 to 0.463)	0.577

*A sensitivity analysis, omitting the 10 patients who did not receive the intervention, was conducted and obtained similar results.

**Analysis by Mixed Models Repeated Measures using STATA v 13

Table 3 Analysis of Secondary Outcomes at Four Month Follow-up

SECONDARY CONTINUOUS OUTCOMES*

	Intervention		Control		Beta Coefficient (95%)*	P Value
	T1 (n=86)	T2 (n=73)	T1 (n=77)	T2 (n=67)		
Health Status (1=low to 66+=high)						
Physical	34.09 (11.851)	36.61 (10.670)	34.16 (10.474)	37.05 (11.995)	0.274 (-2.775 to 3.323)	0.860
Mental	42.66 (13.592)	43.86 (13.506)	44.01 (13.783)	46.23 (13.119)	-1.402 (-5.055 to 2.251)	0.452
Quality of Life (-1 to +1)	0.66 (0.247)	0.66 (0.257)	0.67 (0.246)	0.64 (0.237)	0.037 (-0.034 to 0.109)	0.307

**Analysis by Mixed Models Repeated Measured using STATA v 13*

SECONDARY DICHOTOMOUS OUTCOMES**

	Intervention		Control		Odds Ratio (95% CI)	P Value
	T1 (n=86)	T2 (n=73)	T1 (n=77)	T2 (n=67)		
	%	%	%	%		

Psychological Distress (yes)	18.60	15.49	19.48	13.64	1.490 (0.241 9.197)	0.668
Health Behaviours (yes=healthy behaviour)	%	%	%	%		
Alcohol (no)	42.86	39.73	42.86	38.81	1.161 (0.143 to 9.453)	0.889
Physical activity (2+time per week)	41.86	57.53	53.25	59.70	2.197 (0.595 to 8.110)	0.237
Healthy eating (good-excellent)	52.94	63.01	61.04	67.16	1.792 (0.362 to 8.882)	0.475
Healthy BMI (less than 30)	62.65	56.94	60.81	56.92	0.475 (0.066 to 3.432)	0.461
***multilevel mixed effects logistic regression using STATA v 13*						