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Citation for published version:

Steele, C, Wodchis, WP, Upshur, R, Tahsin, F, McKinstry, B, Mercer, SW, Palen, TE, Ramsay, T, Thavorn, K & Nie, J 2021, 'Assessing the implementation and effectiveness of the Electronic Patient Reported Outcome Tool for Seniors with Complex Care Needs: Mixed Methods Study', *Journal of medical Internet research*, vol. 23, no. 12. <https://doi.org/10.2196/29071>

Digital Object Identifier (DOI):

[10.2196/29071](https://doi.org/10.2196/29071)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Peer reviewed version

Published In:

Journal of medical Internet research

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Title

Assessing the implementation and effectiveness of the Electronic Patient Reported Outcome Tool for Seniors with Complex Care Needs: Mixed Methods Study

Steele Gray C, Wodchis WP, Upshur R, Tahsin F, Srinatharan J, Austin T, Cott C, McKinstry B, Mercer SW, Palen T, Ramsay T, Thavorn K, Nie J

Abstract

Background: Goal-oriented care is being adopted to deliver person-centred primary care to older adults with multimorbidity and complex care needs. While this model holds promise, implementation remains a challenge. Digital health solutions may enable processes to improve adoption, however, they require evaluation to determine feasibility and impact.

Objective: This study evaluates the implementation and effectiveness of the electronic Patient Reported Outcome (ePRO) mobile application and portal system, designed to enable goal-oriented care delivery in inter-professional primary care practices. The research questions driving this study are: 1) *Does ePRO improve quality of life and self-management in older adults with complex needs*, and 2) *what mechanisms are likely driving observed outcomes?*

Methods: A multi-method pragmatic randomized control trial using a stepped-wedge design and ethnographic case studies was conducted over a 15-month period in 6 comprehensive primary care practices across Ontario with a target enrolment of 176 patients. The 6 practices were randomized into either early (3-month control period; 12-month intervention) or late (6-month control period; 9-month intervention) groups. The primary outcome measure of interest was the Assessment of Quality of Life-4D (AQoL-4D). Data were collected at baseline and at 3 monthly intervals for the duration of the trial. Ethnographic data included observations and interviews with patients and providers at the mid-point and end of the intervention. Outcome data were analyzed using linear models conducted at the individual level, accounting for cluster effects at the practice level, and ethnographic data was analyzed using qualitative description and framework analysis methods.

Results: Recruitment challenges resulted in fewer sites and participants than expected; only 142 of the 176 eligible patients were identified due to lower than expected provider participation and fewer than expected patients willing to participate or perceived as ready to engage in goal setting. Of 142 patients approached, 45 patients participated (32%). Patients set a variety of goals related to self-management, mental health, social health and overall well-being. Due to underpowering, the impact of ePRO on quality of life could not be definitively assessed; however the intervention group, ePRO plus usual care ($M = 15.28$, $SD = 18.60$), demonstrated non-significant slight decrease in quality of life, $t(24) = -1.20$, $P = 0.24$, when compared to usual care only ($M = 21.76$, $SD = 2.17$). The ethnographic data reveals a complex implementation process, in which the meaningfulness (or coherence) of the technology to individuals lives and work acted as a key driver to adoption and tool appraisal.

Conclusion: This trial experienced many unexpected and significant implementation challenges related to recruitment and engagement. Future studies could be improved through better alignment of the research methods and intervention to the complex and diverse clinic settings, dynamic goal-oriented care process, and readiness of provider and patient participants.

Trial Registration: ClinicalTrials.gov NCT02917954;
<https://clinicaltrials.gov/ct2/show/NCT02917954?intr=eipro&cntry=CA&rank=1>

Keywords: older adults, goal-oriented care, quality of life, self-management, primary care, eHealth, pragmatic trial

Introduction

Background

The rising population of older adults with multi-morbidity and complex care needs requires health systems adjust to meet this new demand [1, 2]. Complex care needs of patients goes beyond multi-morbidity alone, as these individuals will experience bio-psycho-social challenges and barriers that make it more difficult for them to manage their multiple chronic physical and mental illnesses [14, New Ref 4]. Increasingly, digital health solutions are being adopted to support this patient population, through tools that enable medication management [3], information sharing [4], care planning [5], chronic disease management and monitoring [6, 7], and virtual care tools, particularly since the onset of the COVID-19 pandemic [8]. Of particular use to older adults with complex care needs are solutions that enable person-centred and holistic care delivery to better address the multiple health and social care needs of this population [9-16]. While a person-centred approach has been identified as a priority [15], organizations and providers continue to struggle with how to put the vision of person-centred care into practice [17].

Person-centred care may be operationalized by adopting a goal-oriented care (GOC) approach which involves eliciting patient-identified goals to drive care planning and decision-making [11, 12, 18, 19]. Effectively this model of care shifts from asking a patient “what is the matter with you?” to “what matters to you?” [20] From a patient perspective, GOC represents a more meaningful and holistic approach to care and decision-making [21]. Emerging studies of GOC report reduced treatment burden for patients with multiple chronic conditions [22], and reductions in acute inpatient days and mortality [23]. The pragmatic trial of the Health TAPESTRY program, a digitally-enabled community-based GOC program, evaluated impact on of the program on goal attainment, self-efficacy, quality of life, optimal aging, social support, empowerment, physical activity, falls and access. Finding from this study showed a demonstrated a shift from reactive to proactive care [24]; however, this study, like many other studies of person-centred care [25, 26], Health TAPESTRY did not demonstrate an impact on patient outcomes.

Among the challenges in evaluating an approach like GOC, in particular a digitally-enabled GOC model, is that it is a complex intervention, being delivered to a complex patient population, within a complex system. Conventional methods, like randomized control trials, that apply rigid methods and rely on assumptions of linear cause-effect perspectives [27] may result in ‘controlling’ for the variables that we need to capture [28]. Greenhalgh and Papoutsis instead suggest methods that adopt a systems mindset that allows for adaptability, iteration, and design-thinking better suited to capturing “changing interrelationships between parts of the system.”[27] The evaluation presented in this paper adopts this systems mindset to evaluate the electronic Patient Reported Outcome (ePRO) tool; a novel mobile device and linked portal system that enables GOC delivery to older adults with complex care needs receiving care in interdisciplinary primary care practices. This evaluation is the latest iteration of a multi-phased developmental evaluation of ePRO which took place in Ontario, Canada from April 2018 - June 2019.

Objective and research question

This developmental evaluation incorporates a pragmatic stepped-wedge cluster trial with embedded ethnographic case studies, building on previous stages of design, development, and testing [29-32] (see Figure X.1 for a visual representation how this work builds on previous

stages). This work expands findings from our exploratory trial [32] as a means to engage in what Tsoukas terms “conjunctive theorizing” to generate “rich pictures of complex phenomena by drawing together different kinds of data from multiple sources” [33]. The presented work is guided by the following research questions:

1. *Does ePRO improve quality of life and self-management in older adults with complex needs?*
2. *What mechanisms are likely driving observed outcomes?*

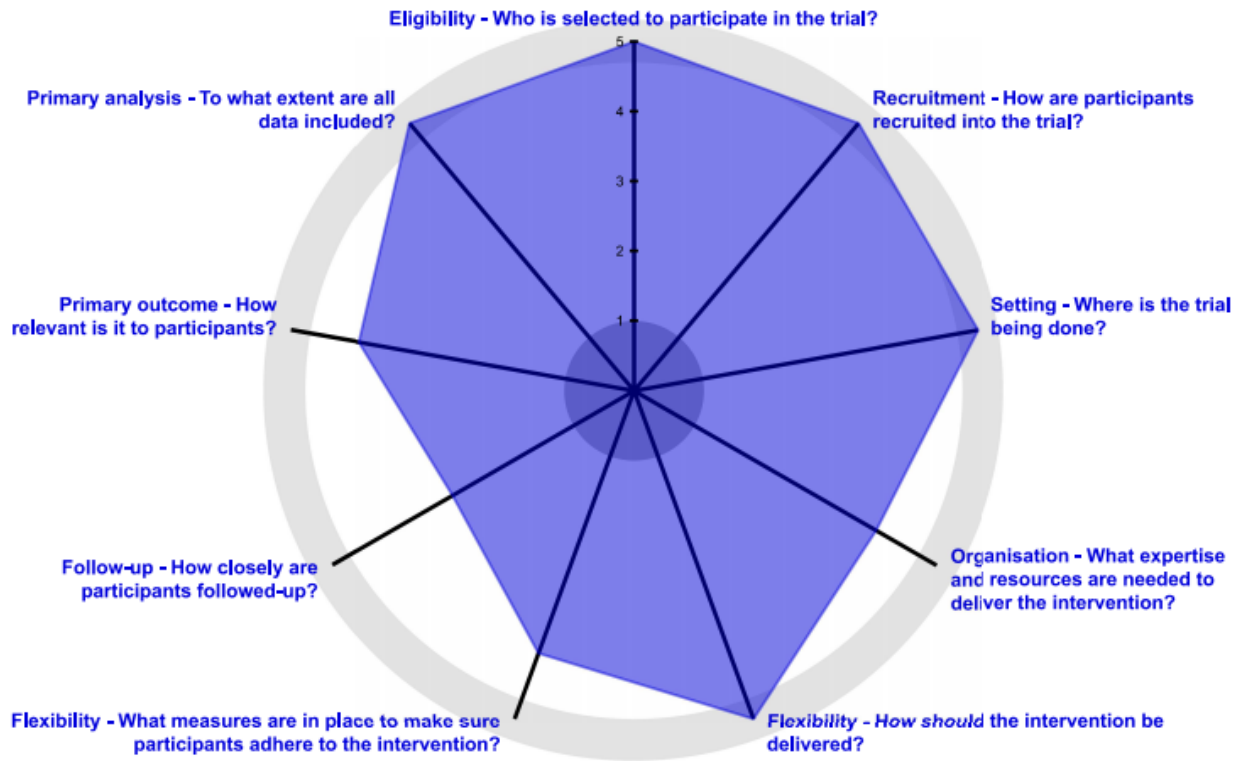
Regarding the first research question, it is hypothesized that the ePRO tool will have a positive impact quality of life and patients’ ability to self-manage.

Methods

Design

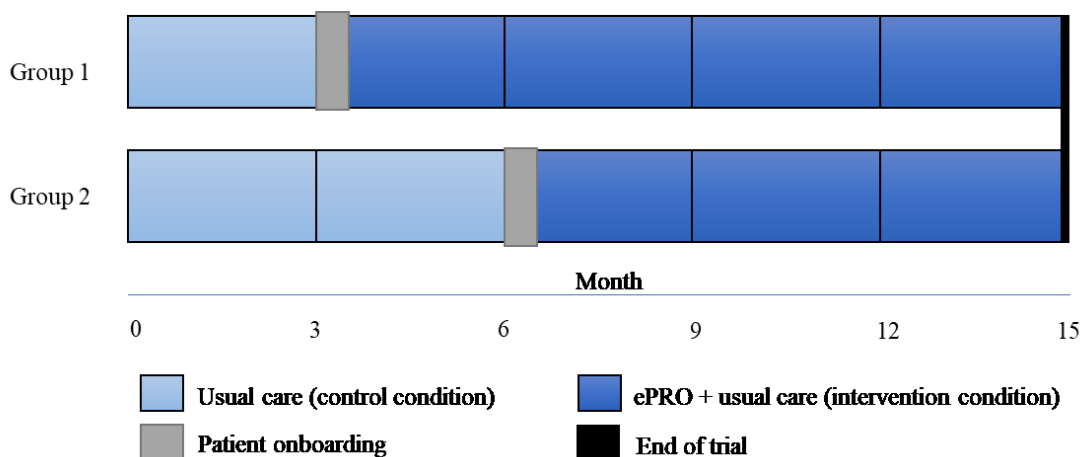
Aligned with Medical Research Council guidelines for evaluating complex interventions [34], a developmental evaluation approach applied; collecting outcome, process and context measures to support decision-making and technology modifications [35]. A pragmatic stepped-wedge cluster randomized trial design was used to assess the effectiveness of the ePRO tool [36]. See PRECIS-2 wheel New Figure 1 describing the degree to which the trial represents a pragmatic design. This design was the most feasible and appropriate approach given the nature of the intervention, time and resources available [37], and desire to compete the study in a real-world setting [38]. An embedded ethnographic case study was included, aligned the methods outlined by Greenhalgh and Swinglehurt’s[39] for evaluating complex technological innovations. The case studies offer rich contextual and process information that accounts for complex interrelationships between variables that would be missed by looking at outcome data alone.

New Figure 1. PRECISE-2 Wheel for ePRO trial



The trial was conducted in six comprehensive primary care practices called Family Health Teams (FHTs) across Ontario, Canada over a 15-month period. Following the stepped-wedge design, all FHTs sites started in the control period where recruited patients all received usual care (no change to their care delivery from the primary care team). A random number generator assigned sites to either the early intervention (n=3 sites) or late intervention (n= 3 sites) group. The early intervention group (Group 1) were assigned to the intervention for 12 months after the initial three-month control period. FHTs in Group 2 switched to the intervention group for nine months after a six-month control period. Figure 1 offers a diagram of the stepped-wedge design.

Figure 1. Stepped-wedge design for ePRO evaluation



Intervention: The electronic Patient Reported Outcomes tool

The ePRO tool was developed via multi-phased user-centred co-design methods and represents an important divergence from many available systems that are single disease focused and/or enhance existing provider-led models of care. The tool is designed to encourage a shift in care process towards a person-centred model through enabling the full goal-oriented care process, including goal elicitation, ongoing monitoring, and goal-modification[40]. Consistent with co-design methods, the tool was iteratively developed with input from patients with complex care needs, their caregivers and a multi-disciplinary primary care team [29,30]. The tool has undergone usability testing [31] as well as an exploratory trial [32]. Findings from these studies were used to update and adapt the tool to user needs and primary care setting. At the time of the trial the ePRO tool did not connect to other existing technology systems (such as EMRs or other available platforms), however the system is built so interoperability would be possible. See Multi-media New Appendix

Population and setting

A two-stage sampling strategy was implemented, first recruiting FHTs, followed by complex patients within each FHT. FHTs in Ontario are similar to Patient-Centred Medical Homes in the United States, in that they both seek to provide comprehensive primary care services through a physician-led multidisciplinary team [42]. Working in collaboration with the project’s decision-making partner, the Association of Family Health Teams of Ontario (AFHTO, representing all 184 FHTs in Ontario), a multi-pronged FHT recruitment strategy was pursued including: 1) email invitations sent to AFHTO member sites; 2) a webinar session with AFHTO quality improvement specialists who could identify eligible sites; and, 3) an information booth at the annual AFHTO conference (October 2016 in Toronto, Ontario) where study information was shared with delegates. From these avenues 29 sites expressed interest to be assessed for eligibility, with six FHTs agreeing to participate (see Figure 2 CONSORT Flow diagram of site recruitment). As FHTs were geographically diverse there was no chance of cross contamination of providers across different sites. Characteristics of the participating sites, as compared to FHTs across Ontario, are summarized in Table 1, and the population densities of the regions are depicted in Figure 3.

Figure 2. CONSORT Flow Diagram – Family Health Team recruitment [updated]

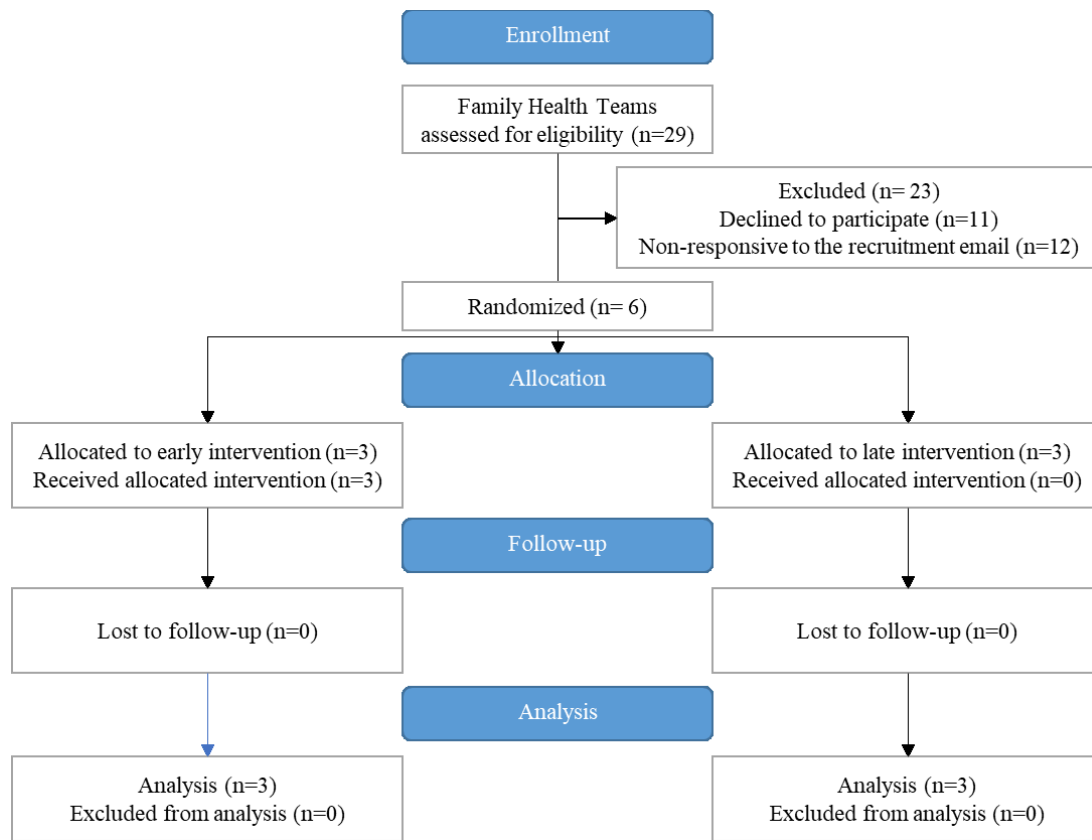


Table 1. Family Health Team characteristics [updated]

Characteristics	Group 1 n (total n in clinic, %)			Group 2 n (total n in clinic, %)			Ontario FHTs
	Site A	Site D	Site E	Site B	Site C	Site F	
Number of providers enrolled in the ePRO study (n)							
Total number of providers*	9 (13, 69%)	4 (18, 22)	6 (22, 27)	1 (17, 6)	2 (12, 17)	7 (13, 54)	Not Available
GPs	0 (4, 0%)	1 (12, 8)	1 (14, 7)	1 (11, 9)	2 (9, 22)	6 (8, 75)	13.53(17.72) ^a
NPs	8 (8, 100%)	1 (3, 33)	4 (6, 67)	0 (4, 0)	0 (2, 0)	1 (NA)	2.65 (3.04)
RD	1 (1, 100%)	2 (2, 100)	1 (1, 100)	0 (1, 0)	0 (1, 0)	0 (NA)	1.19(1.63)
Pharmacist	0 (NA)	0 (1, 0)	0 (1, 0)	0 (1, 0)	0 (1, 0)	0 (NA)	0.63(0.99)
Characteristics of the FHT							
Geographic location of FHT	Rural	Urban	Urban	Medium Urban	Medium Urban	Rural	
Rural n(%)							64 (36)

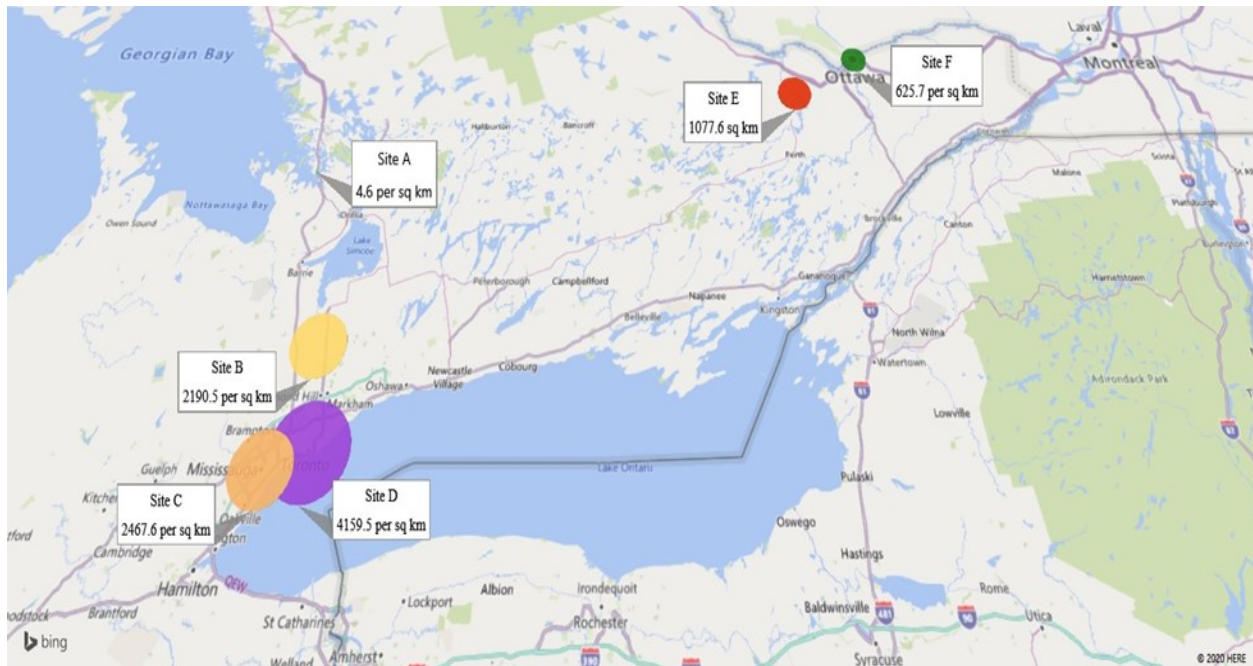
^a Information available from 165 FHT across Ontario

Abbreviations: GPs (General Practitioners); NPs (Nurse Practitioners); RD (Registered Dietitian); NA not available

NOTE: Site names were assigned based on the timing of recruitment

Providers eligible to join the study had to be providing care to patients rostered at the FHT. Providers could be employed full-time, part-time or casual.

Figure 3: Population Density across the regions (persons per square km) Source: Statistics Canada 2016 Census [43]



Patient recruitment and eligibility criteria

Patient recruitment followed exploratory trial procedures, using practice electronic medical records (EMRs) to identify patients 60 years or over with 10 or more visits to the FHT within the previous 12 months. This number of visits has been identified as an indicator of complexity in previous studies [REF1] and guided the recruitment strategy for the exploratory trial [32]. Age 60 was chosen as a cut off over 65 as the study's site leads and primary care knowledge user partners identified that many individuals, in particular those living in rural settings, experience complex care needs at an earlier age. EMR generated patient lists were given to providers to assess whether these individuals met additional eligibility criteria including:

- perceived willingness to engage in goal-oriented care conversations
- ability to use a smartphone or tablet in English or have a caregiver who could do this on their behalf
- capable of providing consent to participate
- willing to complete surveys every three months thereafter until the trial concluded.

Previous studies have identified the provider knowledge of the patient is often necessary to identify complexity given the high degree of patient variability[37]. Posters describing the study were hung in waiting rooms at sites, and the study was presented at Chronic Disease Management Programs that targeted patients with chronic disease and complex care needs for patient self-identification. Some patients self-identified as eligible after presentations at the programs but none came to the study via posters. Recruitment materials and processes were built on what was learned from the exploratory trial and were reviewed and modified by the projects patient partner. Recruitment occurred during a scheduled office visit or by phone by a Research Coordinator assigned to that site. Patient and provider consent was obtained prior to randomization.

Sample size

Minimum sample size required for the recruitment of sites and patients was determined using closed-form analytical formulae with a power of 80% based on: a minimal clinically important difference of our core measure of quality of life (the AQoL-4D) of 0.06 [44], an expected standard deviation in AQoL of 0.22[45], an expected ICC of 0.01 (calculated based on total primary care utilization over a one year period among a 10% sample of the Ontario population, which served here as a proxy measure for patient outcomes), and an expected attrition rate of 10% (rated based on previous studies in similar population groups using similar technology[46]). A minimum sample size of 176 patients was calculated, with a target of recruiting 29 patients per site.

Technology training

Providers and patients were trained on the tool prior to switching from the control to the intervention during an onboarding session. Training for providers was done at the clinic level, where providers from the same clinic were trained in groups at their clinic where they were presented the technology by a research team member and walked through setting up goals for a mock-patient. Patients were trained one-on-one with a research team member on how to use the mobile device just prior to their onboarding visit with the provider. Providers and patients were also provided with user manuals (available at <https://www.eprobridgepoint.com/resources>) and contact information for the research team for technology support.

Data Collection

Context, process, and outcome data were collected via patient-reported surveys, interviews, ethnographic observations, and chart audit. Survey and chart audit data was collected across all 6 sites, while qualitative data was collected at the 3 case sites (sites A, E & F). Four of six agreed to participate as case sites; 1 dropped out as a case site due to low patient recruitment.

Patient-reported surveys

The primary outcome was health-related quality of life measured using the Assessment of Quality of Life – 4 Dimensions (AQoL-4D) [47]. The AQoL-4D is a 12-item questionnaire that addresses the activities of daily living, mental health, relationships with others, and physical sense aspects of a patient's quality of life. AQoL-4D responses were aggregated to generate a raw, continuous score with higher scores indicating greater quality of life. The secondary outcome, self-management, was measured using the 13-item Patient Activation Measure (PAM), measuring the extent to which a patient is activated in their own care [48]. PAM is considered a valid and reliable metric of patient self-management for older adults with multimorbidity [48,

49] [New Ref 2]. PAM generates a score from 0 to 100, with higher scores indicating greater activation (patients are better able to manage their care) [50]. Outcome data were collected at baseline and every subsequent 3 months until the end of their trial. For three patients in Group 2 who enrolled in the study late, outcomes data were collected between October 2018 to June 2019. See Supplement A for the data collection schedule.

Patient and provider demographic information was collected at baseline. A chart review was conducted post-trial to collect missing data in the patient demographic forms, in particular number of types of chronic conditions and medications.

Interviews

Semi-structured interviews were conducted with patients, providers, and managers at case sites at the mid-point (6 months for sites A & E, and 4.5 months for site F) and end of the trial.

Interviews were conducted by research team members trained in qualitative data collection, with initial interviews conducted in pairs to ensure consistency in approach. **The interview guide was developed to capture experiences of patients, providers and managers using the tool or engaged with the trial. Probes were used to delve into implementation factors found to be important to the intervention in the exploratory trial, for example patient-provider relationships and team environment [32]** (see Appendix X for sample questions from the interview guide). Interviews were conducted in person (with one follow-up mid-point interview was conducted over the phone), lasted between 20-60 minutes and were audio recorded and transcribed verbatim.

Ethnographic observation

Ethnographic observations of case sites occurred at multiple points throughout the study, mainly when conducting other activities such as training, patient onboarding, and interviews. At these points a member of the research team would observe the clinic visit between the patient and provider. Providers were also encouraged to inform the team when patients were coming in for visits so that additional “ad hoc” observations could be conducted; however no such invitations occurred. Field memos were taken during and just after observation periods. Field note guides helped research staff attend to contexts and processes anticipated to be relevant based on findings from the exploratory trial. Observations were conducted by Research Coordinators who had graduate training in qualitative health services methods and/or were provided training by the project lead in the approach. For coordinators newer to the method observation debriefs and field memo reviews were conducted by the lead to provide ongoing training and skill building.

Usage logs

Usage logs from the ePRO tool were used to track tool use and types of goals set by participants. Goals were categorized into types using a qualitative content analysis. Tool use was determined via number of interactions defined as any log-in or data entered into the system; participants completing one interaction in a given month were considered “active” that month. The total number of active participants was calculated monthly to categorize participants into long-term (using the app for 3 or more months), short-term (using the app for less than 3 months), or non-user (participants who did not use the app after initial onboarding) groups. The 3-month cut-off is consistent with previous mHealth clinical trials [51]. Usage categories helped interpret qualitative and quantitative findings.

Data Analyses

Statistical analysis

Descriptive statistics were calculated for the cohort stratified by groups of FHTs, using counts and means (SD) for categorical and continuous variables respectively. To estimate the degree to which ePRO tool plus usual care affects health-related quality-of-life and self-management relative to usual care alone, linear models were fitted with exposure identified by a fixed effect ordinal variable of calendar time (accounting for staggered implementation) and adjusting for clustering at the FHT site level [52]. The primary effect estimates are summarized as the mean differences for continuous outcomes. Each comparison was evaluated with a two-sided test and evaluated at the nominal significance level of $\alpha = 0.05$. Statistical analyses of outcome data were performed under the intention to treat principle. All descriptive analyses and multi-level modelling were completed with the Stata 15.1 statistical software. Due to the size of the dataset, mixed effects models that included covariates such as age, sex, income level, rurality, chronic disease management, and number of chronic conditions could not be included into the modeling.

While missingness in cluster randomized trials in primary care can be handled via multiple imputation methods, using any such imputation for estimating the absence of data points in the cohort was deemed inappropriate due to the high degree of missingness so analyzed only the data that was collected from the surveys [New Ref 7 & 8]. Aligned with the intention to treat approach, individuals were not excluded from the analysis based on their non-responses to the survey; only variables were excluded, not individuals.

Interview and observation data

Interview and observational data were used to address the second research question, and were analyzed using inductive qualitative descriptive [53] and narrative descriptive methods [54], with separate analyses conducted for patients and provider interviews. Manager interviews were coded with provider data as they were asked similar questions and addressed many of the same implementation constructs in their interviews. Consistent with this method, codes that described dominant themes within participant groups were identified. Coding was conducted by researcher pairs trained in qualitative methods to support validation. Observational memos were coded with the patient interviews and were also reviewed as part of the analytic process to provide context information where appropriate to guide interpretation. All team members involved in qualitative data collection and analysis were trained in attending to reflexivity in their approach and all kept fulsome analytic memos to track their own positionality with regard to the qualitative analysis.

To support directed analysis for the purposes of this evaluation, a deductive approach was used to map descriptive codes to Normalization Process Theory (NPT) [63] to understand implementation mechanisms. Exploratory trial findings suggest NPT is a likely theory of change underpinning this intervention [32]. NPT suggests that new processes become embedded as part of actors' routines through the social production of work, enabled through 4 generative mechanisms: coherence, cognitive participation, collective action, and reflexive monitoring (see descriptions of concepts in Table 7). These four NPT constructs were applied to descriptively coded patient, provider and manager interview and observational data, and cross referenced with patient user groups (long, short, non) and case site characteristics to generate insights regarding factors that drove implementation and outcomes. . Data coded to relevant themes were extracted and organized using tables using a framework analysis approach [55] to identify patterns and

trends. Tables were reviewed by the research team as part of qualitative validation (supporting credibility and trustworthiness). NVivo 11 software was used to manage data in the initial coding phase, Excel and Word files were used to organize data from framework analysis.

Integrating quantitative and qualitative data

Integration of quantitative and qualitative data sets followed a *convergent design* which involves collecting all sources of data concurrently, separately analyzing data, then comparing results through interpretation and discussion of findings [56, 57].

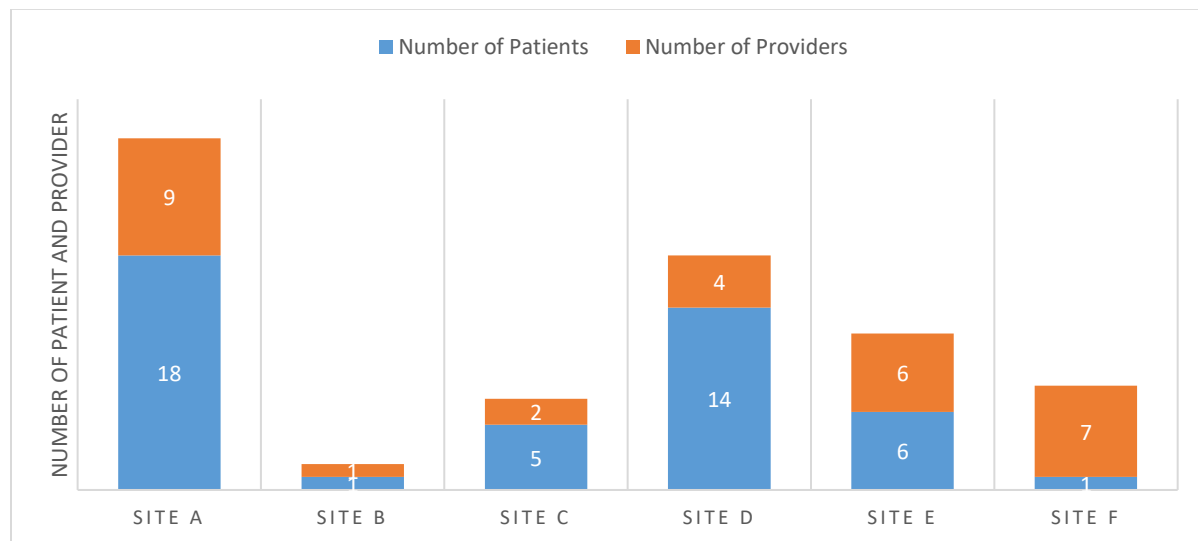
Ethics

Research ethics approval was granted by the University of Toronto's Health Sciences Research Ethics Board (#33944) and the ethics committees of all participating practices.

Results

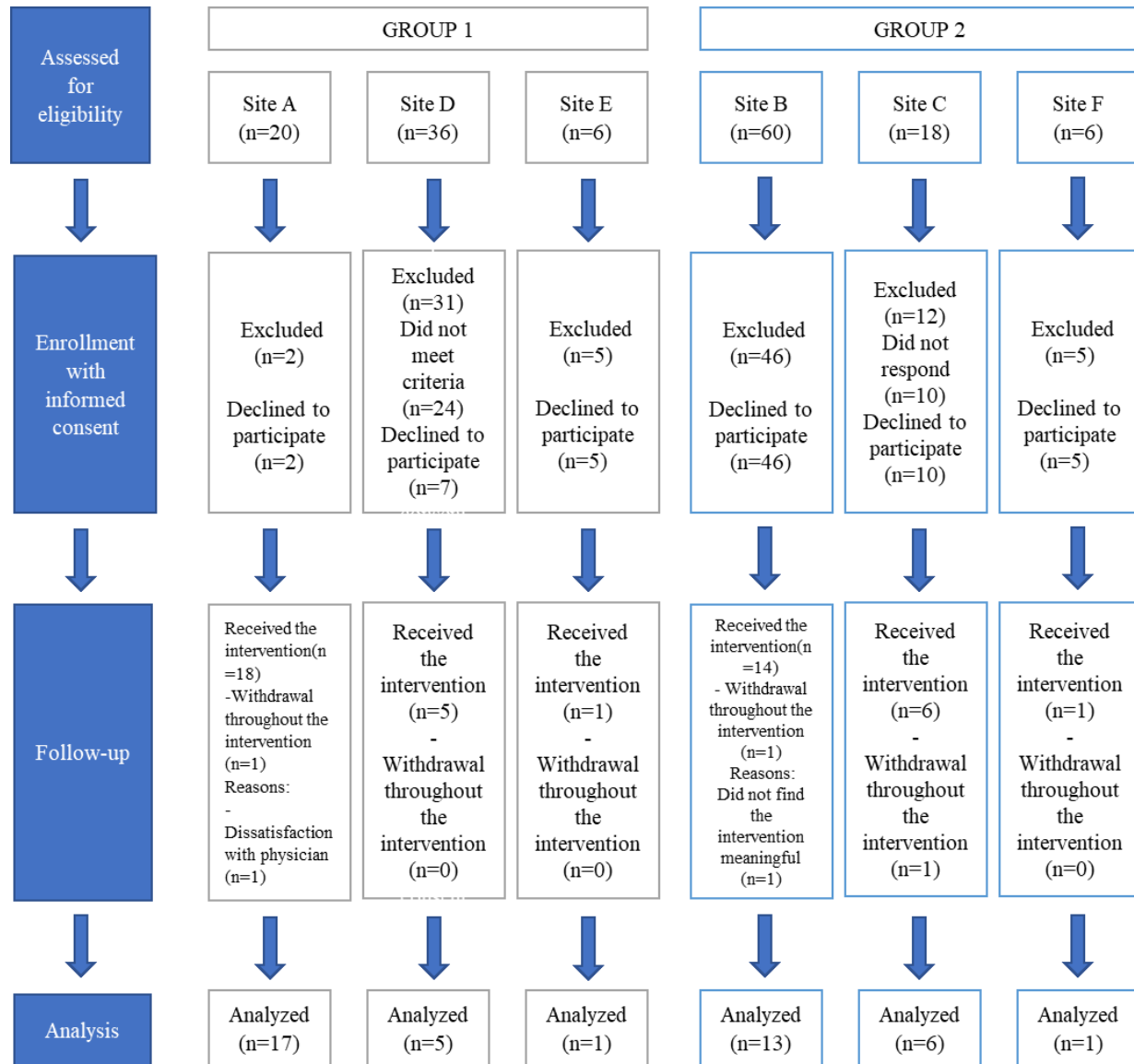
Participant recruitment

Figure 5. Number of providers and patients participating at each site.



While the study design target was 176 patients only 142 were identified as eligible and approached (see discussion section for elaboration on this point). Of the 142 approached 46 consented to participate. One participant withdrew prior to any data collection, leaving 45 patient participants. This relatively low acceptance rate (32%) was an additional challenge. Patient reported reasons for not participating included: perceiving they did not have complex or chronic conditions, lack of time, perceived conflicts with other life responsibilities (e.g., planned vacations and travel), feeling as though they did not have a goal to work on, or uninterested in this research. Three patients dropped out of the study one due to decline in health condition making it difficult to participate and two because of loss of interest in participating. See Figure 4 for the CONSORT flow diagram depicting patient recruitment.

Figure 4. CONSORT flow diagram of patient recruitment arranged by Group



Participant characteristics and goals set

Patient demographics are summarized in Table 2 presented by randomized groups to allow for between group comparisons. There was a statistically significant difference in rurality and socioeconomic status between the groups.

Table 2. Baseline characteristics of the cohort of Family Health Team patients with complex chronic diseases and disabilities (n = 44) [updated]

	Group 1 (Site A, Site D, Site E) (n = 23)	Group 2 (Site B, Site C, Site F) (n = 21)	P value
Age (mean/SD)	68.65 (7.10)	71.98 (6.20)	0.08
Sex, n (%)			0.07
Female	15 (65.22)	7 (33.33)	
Male	8 (34.78)	14 (66.67)	

Place of residence, n (%)			0.08
Urban	9 (39.13)	14 (66.67)	
Rural	14 (60.87)	7 (33.33)	
Living alone, n (%)			0.36
Yes	10 (43.48)	6 (28.57)	
No	13 (56.52)	15 (71.43)	
Born in Canada, n (%)			0.17
Yes	19 (82.62)	13 (61.90)	
No	4 (17.39)	8 (38.10)	
Family income^a, n (%)			0.04
\$0-29K	7 (30.43)	1 (4.76)	
\$30-\$59K	7 (30.43)	5 (23.81)	
\$60-\$89K	2 (8.70)	8 (38.10)	
>\$90K	7 (30.43)	7 (33.33)	
Education^b, n (%)			0.02
Less than high-school	4 (17.39)	1 (4.76)	
High-school	4 (17.39)	1 (4.76)	
Some college/university	9 (39.13)	4 (19.05)	
University (Undergraduate, Graduate)	6 (26.09)	15 (71.43)	
Ethnicity, n (%)			0.43
East Asian	0 (0.00)	1 (4.76)	
South Asian	1 (4.35)	0 (0.00)	
Metis	0 (0.00)	1 (4.76)	
White (North American, European)	21 (91.30)	17 (80.95)	
Mixed heritage	1 (4.35)	2 (9.52)	
Chronic disease management program, n (%)			1.00
Yes	6 (26.09)	2 (9.52)	
No	1 (4.40)	1 (5.00)	
Missing	16 (69.57)	18 (85.71)	
Total number of chronic conditions (mean/SD)	4.21 (2.00)	3.20 (2.00)	0.0001
Chronic conditions diagnoses, n (%)			
Arthritis	7 (30.43)	2 (9.52)	
Asthma	5 (21.74)	3 (14.30)	
Atrial fibrillation	1 (4.40)	2 (9.52)	
Cancer	8 (35.00)	3 (14.30)	
Chronic obstructive pulmonary disease	10 (44.00)	2 (9.52)	
Congestive heart failure	0 (0.00)	0 (0.00)	
Diabetes	10 (44.00)	3 (14.30)	
Enlarged prostate	0 (0.00)	6 (29.00)	
Epilepsy	1 (4.40)	0 (0.00)	
Gastroparesis	1 (4.40)	0 (0.00)	
Hypercholesterolemia	13 (56.52)	4 (19.04)	
Hypertension	15 (65.22)	8 (38.10)	
Hypothyroidism	3 (13.04)	0 (0.00)	
Ischemic heart disease	0 (0.00)	2 (9.52)	
Kidney failure	2 (9.00)	1 (5.00)	
Macular degeneration	1 (4.40)	0 (0.00)	
Mental health conditions	1 (4.40)	0 (0.00)	

Pain	6 (26.10)	6 (29.00)
Sleep apnea	2 (9.00)	3 (14.30)
Stroke	4 (17.40)	3 (14.30)
Urinary retention	0 (0.00)	0 (0.00)
Other ^c	5 (21.74)	6 (29.00)

Note: Balance in the distribution of covariates between group 1 and 2 Family Health Team sites was assessed with Kruskal Wallis and Fisher's exact test. Percentages may not equal 100.00% due to rounding.

^aFamily income prior to taxes in Canadian dollars.

^bIndividual has completed or is considered an undergraduate and/or graduate student.

^cMood disorders (anxiety, depression), multiple sclerosis, acute myocardial infarction, peripheral vascular disease, peripheral neuropathy, and osteoporosis

Patients set a variety of goals related to self-management, mental health, social health and overall well-being and self-care (see New Appendix 1 for a list of goals and tasks). Patient-provider pairs varied in terms of their degree of specificity of the goals they set ranging from highly specific goals (for example walking 20 minutes 3 times per week or losing 10 pounds), to more general goals (for example reducing meat consumption or getting more sleep).

Intervention impact on quality of life and self-management

Missing survey data was substantial ranging between 14-91% mainly due to non-response rather than attrition. There were n = 2 individuals that withdrew during the trial so lost-to-follow up was 4.5%.

Tables 4 and 5 offer descriptive statistics of the AQoL-4D and PAM scores from the sites at each data collection time point, where the greyed boxes are the control periods. Raw AQoL scores overtime suggests most patients (with the exception of those at Site B) started, and remained, relatively healthy over the course of the study (with a notably wide SD).

Table 4: Mean (SD) of patient health-related quality of life at each discrete timepoint

Calendar time	Group 1			Group 2		
	Site A (n = 17)	Site D (n = 5)	Site E (n = 1)	Site B (n = 13)	Site C (n = 7)	Site F (n = 1)
Baseline (January 2018)	19.30 (10.10)	22.22 (20.03)	6.00	10.61 (6.78)	28.00 (16.78)	17.00
Period 1: April – July 2018	20.94 (7.32)	28.47 (10.72)	6.00	11.11 (11.50)	31.00 (35.40)	6.00
Period 2: July – October 2018	15.83 (7.64)	28.47 (22.00)	-	10.00 (5.74)	37.04 (23.62)	11.11
Period 3: October 2018 – January 2019	18.00 (10.00)	20.83 (25.53)	-	8.00 (8.19)	42.00 (35.40)	17.00
Period 4: January – April 2019;	22.83 (12.94)	28.70 (13.13)	-	10.42 (9.00)	8.33 (8.00)*	22.22
Period 5: April – July 2019	11.11 (3.00)	36.11	-	-	-	-

AQoL scoring 0-45 with 45 being the worst possible health

Note: Mean (SD) quality-of-life scores could not always be calculated for each site and period due to missingness and/or lack of variability in the questionnaire responses. Shading represents usual care (control) period of the intervention.

* For this site there were only 2 respondents in periods 3 and 4. The two who responded in period 3 had a wide spread between scores (16.67 & 66.06) , the 2 respondents in period 4 were both lower overall (2.77 & 13.89).

Table 5: Mean (SD) of patient self-activation scores at each discrete timepoint during the trial

Calendar time	Group 1			Group 2		
	Site A (n = 17)	Site D (n = 5)	Site E (n = 1)	Site B (n = 13)	Site C (n = 7)	Site F (n = 1)
Baseline (January 2018)	60.42 (15.00)	61.10 (9.00)	53.20	63.10 (15.00)	55.00 (11.30)	58.10
Period 1: April – July 2018	60.01 (10.59)	58.80 (8.26)	56.00	72.00 (19.12)	52.10 (1.60)	66.00

Period 2: July – October 2018	70.00 (14.92)	63.10 (10.00)	56.00	69.40 (19.04)	59.20 (9.00)	58.10
Period 3: October 2018 – January 2019	71.79 (20.31)	53.00 (15.00)	-	68.00 (25.82)	56.30 (13.10)	56.00
Period 4: January – April 2019;	68.57 (19.41)	63.00 (4.20)	-	98.00 (5.00)	56.00 (7.00)	61.00
Period 5: April – July 2019	73.57 (13.94)	48.90	-	76.93 (20.54)	-	66.00

Note: Mean (SD) patient self-activation scores could not always be calculated for each site and period due to missingness and/or lack of variability in the questionnaire responses. Shading represents usual care (control) period of the intervention.

After adjusting for the covariate of time in the model, patients with ePRO combined with usual care ($M = 15.28$, $SD = 18.60$) demonstrated non-significant slight decrease in quality of life, $t(24) = -1.20$, $P = 0.24$ and was lower than usual care only ($M = 21.76$, $SD = 2.17$). With regard to patient engagement, ePRO combined with usual care ($M = 66.5$, $SD = 17.3$) demonstrated non-significant slight decrease in patient activation, $t(27) = -1.41$, $P = 0.17$, as compared to usual care ($M = 59.49$, $SD = 9.60$).

No patterns were evident when exploring descriptive trends in outcomes as related to ePRO user intensity (e.g. those who used the tool regularly versus those who rarely used or abandoned it all together). There were fewer completed follow-up surveys in the short-term and non-user groups.

Mechanisms likely driving outcomes: Selected findings from ethnographic case studies

Usage log data revealed significant attrition on the tool for both long and short-term user groups with 46% (21/46) of patients using the tool as intended, 15.2% (7/46) discontinuing use after 3 months and 36% (17/46) abandoning the app after initial training. Data from the ethnographic case studies is analyzed to provide insights into factors that may be driving usage and potentially, influencing outcomes.

Table 6 offers a summary of data sources and Table 7 offers a summary of NPT constructs and analysis.

Table 6. Ethnographic data sources

Case sites	Patient interviews (n=24)	Provider interviews (n=22)	Observations (n=21)
Site A	6 mid-term 5 end of project	6 mid-term 5 end of project	1 onboarding 5 ad-hoc
Site B	3 mid-term 3 end of project	4 mid-term 3 end of project	1 onboarding 9 ad-hoc
Site C	2 mid-term 2 end of project	2 mid-term 2 end of project	2 onboarding 3 ad-hoc

Table 7. Summary of how patients and providers understood, engaged with and reflected on the adoption of the ePRO tool as aligned with Normalization Process Theory constructs.

Coherence			
Beliefs, behaviours and acts that shape an activity as meaningful. Occurs at both the individual (individual specification) and group level (communication specification) and is produced and reproduced through ongoing interaction.			
Patient summary	Exemplary quote	Provider summary	Exemplary quote
<p>Coherence for patients was related to their personal beliefs around setting and achieving goals, their expectations that ePRO could make a difference to their lives, and if they had a clear goal or aim. Several disconfirming examples suggest that these individual specifications of meaning may not be sufficient, and rather communal specification may be more important, which is demonstrated through observation data.</p> <p>For example, two individuals self-identified as goal oriented would suggest greater likelihood of longer-term use. Only one was a long-term user and reported a strong relationship with their provider</p>	<p>"It's (SMART goal) clear, you know, it makes you focus more. It does make you focus more, like any type of goal setting will make you focus more, you think about it more, you know? And...you may question things more, you may do a little more research, you may change your habits like I'm trying to get to bed earlier, because I tend to push it and stay up late and still get up, you know, fairly early. " (Site C, super user, ID01)</p>	<p>The ePRO tool was considered to be coherent when it aligned to the philosophy of providers and their approach to goal-oriented care, and when it was perceived to fit "the right" patient. Coherence to the tool for providers was higher earlier in the trial when they were more engaged with the tool during the onboarding process.</p> <p>Adding technology to "enable" a process requires strong alignment to coherence with that process, not just from a formative standpoint but from a normative one as well (see contextual integration point below).</p>	<p>"I did like that it flowed with the way we think in terms of our level of care and making it very patient centred. And they're smart goals and very achievable and things like that. So I did like that it meshed with our philosophy." (Site A, Registered dietitian, nutrition counselling)</p>

<p>and high confidence with regard to their goal (Site A, ID08). The other, who had just met their provider and reported lower confidence with regard to their goal ended up being a short-term user (Site B, ID13).</p>			
<p><i>Cognitive participation</i> Individuals actively participating with the intervention.</p>			
<p>Patient summary</p>	<p>Exemplary quote</p>	<p>Provider summary</p>	<p>Exemplary quote</p>
<p>All patients engaged initially in the program, but only those who demonstrated stronger belief in ePRO (stronger coherence) continued use. Other influential factors included: being tech savvy, functionality of the tool and relationships with their provider.</p> <p>Notably, when patients saw the role of the provider as pivotal to their understanding of the tool (coherence) and when that went away they discontinued use.</p>	<p>“(Our relationship) has got closer. Being open, being able to say what you’re feeling, what you’re thinking.” (Site A, ID08, long term user)</p>	<p>Cognitive participation was highest during the goal-setting process where coherence was highest for all case sites. However, as the intervention progressed towards collective action a disconnect between how the tool related to the model of care emerged. For providers who viewed GOC as an ongoing collaborative process, the tool continued to make sense (higher coherence). However, for providers who viewed GOC as a self-management process only, provider did not see the value of the tool after the initial set up when their job was</p>	<p>“Once we’ve collaborated and figured the goals out together. The rest I’ve sort of left it up to the patients to dictate how they want to pursue it afterwards. Rather than me kind of bringing it up, or me following it or measuring certain outcomes based on [ePRO]. I primarily use it just for the goal setting aspect.” (Site B, Registered dietitian)</p> <p><i>“And so, once I felt like, OK. I checked in a few times – especially at the beginning, you know two weeks and four weeks or whatever, it may be a phone call – and then I felt like if</i></p>

		perceived to be finished (lower coherence).	<i>they were comfortable with it and they knew where to find me, I kind of just let them do their thing.” (Site A, [Physical Therapist], ID06)</i>
<p>Collective action</p> <p>Where groups start to normalize the process and work together, involved collective purpose aimed at a shared goal. Contextual integration, linking the intervention to existing structures and procedures enables this process.</p>			
Patient summary	Exemplary quote	Provider summary	Exemplary quote
<p>Observation notes suggest that stronger relationships between patients and providers led to better onboarding experiences and stronger coherence with the understanding of the purpose of the tool. Reported as more collaborative and smoother goal setting processes in the onboarding observations. Notably contextual integration for high user patients occurred when they were able to find ways to make the tool a part of their day. There is evidence here as well that patient users were more engaged in the activity</p>	<p>"I mean if it's just for self-monitoring, which is what I began to think it was, that's one thing. But that wasn't how I had pictured it initially...I would think of it differently if I thought it was self-monitoring. I mean the business of why didn't you meet your goals. I would enter a different thing if I thought it was for my own use, I wasn't trying to explain it to some anonymous person that I never heard back from. That's what I never understood, whether there was somebody out there that was going to</p>	<p>Contextual integration was the challenge for providers with regard to the actual use of the tool (integrating into other tools), and their approach to chronic disease management (language, and self-management approach). Some providers who did see the alignment to chronic disease management wanted reminders to improve activation of the intervention – and some established new processes so they could continuously engage with the tool. Relationships were also fundamental to support</p>	<p>“No, it did kind of fizzle out, right, so that in the start up – well, it took a while to get it going and then once we did, I think it was good but then yeah, the challenges are with the patients, right? I’m not going to be calling and bugging them because it’s out of my work – like it wasn’t something – it’s their goals, their ... up to them to do.” (Site A, Registered Nurse, seniors health)</p>

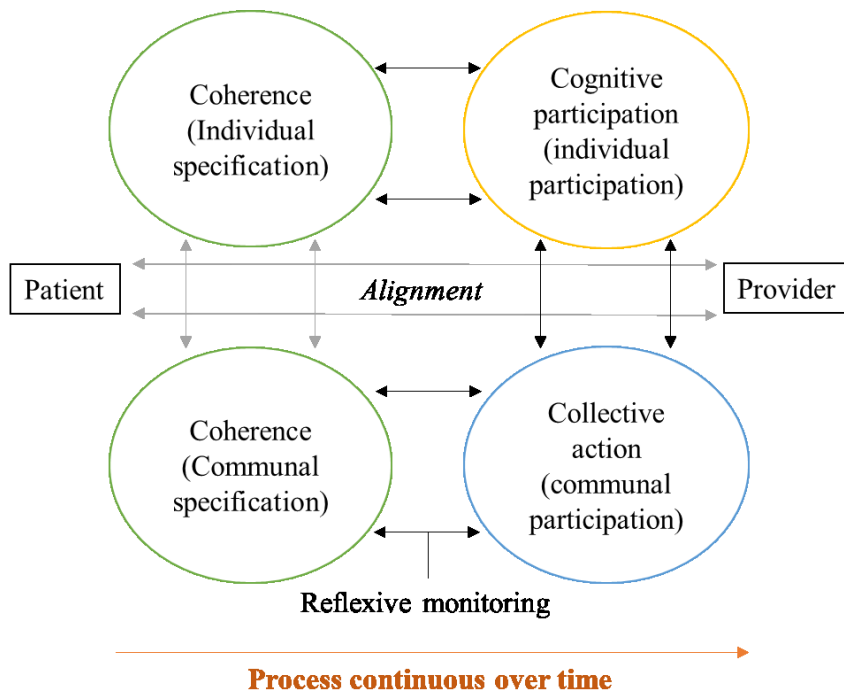
<p>through production and reproduction of the practice of use. Likely as interactions with providers became further away, there was a loss of perceived “collective action” and that may have led to a drop of in the perceived meaningfulness and subsequent use.</p>	<p>speak back to me or not" (Site B, ID12, non-user)</p>	<p>collective action. Provider Site A ID06 notes “people need to know that you care and that you’ve got their back.” – the app being non-responsive actually upends this relational piece which may not have impacted their relationship with the providers, but certainly did with the tool.</p>	
<p><i>Reflexive monitoring</i></p> <p>Individual and groups’ judgments regarding the utility and effectiveness of the new practice. The formality and intensity of monitoring work signals level of embeddedness.</p>			
<p>Patient summary</p>	<p>Exemplary quote</p>	<p>Provider summary</p>	<p>Exemplary quote</p>
<p>For those intrinsically motivated towards their goal it didn’t seem important whether they were using the tool or not, for those less motivated by the goals, however, they judged the tool to be less valuable, particularly if they weren’t receiving any feedback (or additional external motivation). Notably when the tool was no longer judged to be coherent for the patient they disengaged. This also relates back to individual and communal appraisal.</p>	<p>“The phone, I didn’t use at all. I used the computer and that was much simpler. Because I wasn’t putting [my responses] in regularly and you weren’t getting it, I couldn’t really tell what I was doing. Like, I couldn’t see the outcome of what I was doing because I wasn’t putting it in regularly enough. when you couldn’t put it in regularly...That was my big downfall, so I never really got to use it as a tool terribly much.” (Site A. ID03, nonuser)</p>	<p>Providers engaged in regular reflexive monitoring throughout the implementation of the tool often relating their cognitive participation and collective action around the tool to their coherence of the tools value to their work. A number of providers perceived the tool helped with accountability and motivation for patients.</p> <p>This process slowed throughout the study as providers engaged less and less with the tool and had fewer</p>	<p>“Well just to see how motivated she is, the fact that she felt that she was being accountable for her own health and her activity, and then to support her and encourage her to sustain that, and just to re-assess if needed, right?” (Site C, Provider ID03)</p>

		opportunities to assess its value. This is most evident when exploring the changes in provider accounts of value and impact of the tool in mid-term interviews as compared to end of intervention interviews.	
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The role of coherence, cognitive participation, collective action, and reflexive monitoring

Consistent with findings from the exploratory trial, meaningfulness of the ePRO tool to patients and providers had a significant influence on how and when it was used. Revealed in this analysis, is that meaningfulness of the ePRO tool (it's coherence to the participants) changed over time, and was reliant on: 1) alignment to previously held notions of chronic disease management by providers and patients; 2) alignment to daily work and life activities (enabling cognitive participation); 3) strong relationships between patients and providers (enabling collective action); and 4) consistent positive assessments of the tool's utility (regular reflexive monitoring). An additional challenge is the interactional aspect of the ePRO tool which meant that both individual, as well as collective coherence needed to be aligned to the tool as depicted in Figure 6.

Figure 6. Visual depiction of the normalization process of the ePRO tool



The figure offers a simplified illustration of a complex ongoing process, highlighting two key drivers of adoption in this study. First is the need for alignment between how individuals within a shared process understand that process (coherence) and then act on it (cognitive participation and collective action), depicted by grey arrows in the figure. Collective action (the actual use of the tool) proved to be highly influenced by this individual and shared coherence but differed depending on where users were in the process of goal-oriented care. For example, the data demonstrates that collective action occurred more towards the beginning of the intervention during goal setting, when there was better alignment between individual and communal coherence of the intervention. This important time variable is depicted by the orange arrow. Second is that evaluation and assessment of the tool (reflexive monitoring) is continuous and interactive rather than a demonstration of normalization as originally theorized, depicted in Figure 6 as the black bidirectional arrows. As participants moved through participation and

action in using ePRO they would consistently reflect on its individual and collective coherence, assessing whether it was worth continuing. Our data suggests that when alignment is high between individual and group level coherence, there was greater likelihood of ongoing collective action; in this case use of the ePRO tool. This relationship is not currently depicted in the tool as it will need to be tested in future studies.

Discussion

Participants and study implementation

Only 142 eligible patients of the target 176 were identified. Minimum recruitment numbers could not be reached due to three challenges. First, some sites had few provider participants join the study. The usability study and exploratory trial suggested that providers who were just starting with the ePRO tool should only manage a maximum of 5 patients at a time to reduce burden. The recruitment strategy required 6-8 providers to identify 5-10 patients each whom they could manage for the duration of the trial. As such, sites with fewer providers, identified fewer patients to join the study (sites B and C in particular). Second, the requirement that patients be “ready” to engage in goal setting proved a more significant barrier than at previous stages of ePRO testing. Practice EMRs identified many potential patient participants, but when reviewed by providers few were identified as “ready”. Related to this point, is that the stepped-wedge design requires all participants to start an intervention at the same time. This rigid timing created an unanticipated third challenge, described in the “role of the research process” section below.

The patient participants also likely represent a “healthier” group overall. As compared to similar patients in Canada, the United States, Australia and the United Kingdom, patient participants had a lower number of reported chronic illnesses and a higher level of reported education [58-61]. AQoL scores of patients are aligned with previously published population norms [62]. Participants PAM standardized scores demonstrate slightly higher activation levels as compared to similar multimorbid populations; for instance, in a validation study of PAM that found a mean score of 56.6 (SD, 12.9)[49].

Another important point to highlight about providers is the relatively large number of Registered Dietitians and Nurse Practitioners who participated. One systematic review found several examples of dietitian supported Diabetes Prevention Programs [New Ref 5], and Nurse Practitioners have been shown to successfully support digitally enabled chronic disease management programs in outpatient settings [New Ref 6]. These examples, along with findings from this study, suggest an important role for allied health professionals in the implementation of digitally enabled health interventions for chronic disease populations.

Finally, the nature of the research process itself influenced trial implementation and outcome, as it conflicted with the natural process of delivering goal-oriented care. First, providers were exasperated by recruitment challenges which resulted in delays to the trial start date. Second, while having providers manage few patients reduced burden, it also meant providers had fewer opportunities to engage with tool. As time went on, providers began to forget about the tool and why they valued it in the first place. Finally, the stepped-wedge required time-bounded window for patient onboarding. Goal-oriented care, however, is a fluid approach, in which goal setting needs to occur at a point when patients are ready (as noted in the provider data around

coherence). Providers expressed frustration that study parameters of limited their ability to onboard patients later identified as individuals who could benefit from the tool.

Principal Results

Recruitment challenges previously described resulted in the study being underpowered. As such, a conclusion regarding the effectiveness of the ePRO tool cannot be drawn. Analysis of the ethnographic data reveals interrelationships between use patterns, outcome trends, and patient and provider contexts to reveal underlying mechanisms driving this complex intervention. Many patients and providers perceived the ePRO tool as valuable with potential to improve engagement and healthy behaviours, however, over time, this excitement waned. Providers reverted to old ways of working as did some patients. Waning engagement in is not unique to digital health and has been in other behaviour change interventions. Other patients for whom the tool was well aligned to their values and aims for managing their health demonstrated longer term adherence. For those “high-users” whose coherence of the tool was tied to their interaction and relationship with their provider, they too began to fall away from the intervention as providers became less involved.

These findings uncover two tensions that have implications for digital health interventions for patients with complex care needs and multimorbidity in a primary care setting.

Challenge #1: Supporting engagement in the intervention over time

Engagement with an intervention is a well document challenge in primary care. Studies of medication adherence show similar ranges of adherence (40-60%) [64, 65] for chronic disease populations in primary care settings (ePRO adherence was 44%). “Non-adherence” reduces exposure and can lessen the effect of the intervention [66, 67]. However, this lens suggests that it is the patient’s fault for not doing as they are told, rather than placing a critical lens on the intervention itself. Perhaps a more useful lens is to consider engagement both “1) the extent (e.g. amount, frequency, duration, depth) of usage and 2) a subjective experience characterized by attention, interest and affect.” [68] .

The ePRO tool experienced low retention rates typical of many mHealth interventions [69], which is connected to both usage and subjective experience. The ethnographic findings suggest that subjective experience is linked to patient coherence and meaningfulness of the tool. This finding is consistent with other studies that have shown that psychological factors such as motivation, expectations of the app, mental health, cognitive burden and personal relevance will influence patient engagement [68]. Usability of the technology and tech savviness of users can often act as a barrier to ongoing use [NEW REF 3]. The usability analysis for this trial was too extensive an in-depth to include in this paper. One key finding from that analysis is that tech savviness and usability issues were moderated by patient-provider relationship, in that patients with stronger regular connections to their providers were more likely to troubleshoot and work through technology challenges regardless of reported “savviness” [Forthcoming].

Importantly in this study, is how app burn-out occurred for patients *and* providers, for whom attrition was similarly linked to reduced usage and subjective experience. Primary care providers too have demonstrated declining engagement with interventions over time, an issue identified in the literature as clinical inertia [70]. With continuous interventions, like GOC, the ePRO study findings suggest that tapping into coherence consistently may improve engagement by both patients and providers.

Challenge #2: Meaningfulness for the individual vs. the group

Alignment of the ePRO tool to what was important and meaningful to patients and providers (coherence) was foundational. Study findings lends support for the importance of meaningfulness in technology [71], but also demonstrates how meaningfulness is constructed at both the individual and group levels, as suggested by NPT [63]. The disconnect between how providers and patients approached GOC is likely a contributor to abandonment of the tool by those patients who sat somewhere between the strongly self-motivated super users, and somewhat indifferent non-users. For patients, GOC was a way to motivate and feel accountable for goals co-constructed with their providers. For many providers, however, GOC was an approach to support patient self-management which did not require the same amount of ongoing connection and feedback expected from patients. This view is well represented by the quote from the Physical Therapist at site A available in Table 7 under the cognitive participation domain.

This approach to self-management suggests a provider plays the role of consultant, guiding patients through the management of their illnesses[72]. While there is room for collaborative care and goal setting in this model, the emphasis is on setting patients up to succeed then sending them off. The qualitative data from this study suggests patients wanted more of a “coaching” approach with more touch points and interactions to maintain momentum, particularly for patients who started strong but then fizzled out. Theories of volition and self-regulation suggest that “feedback focused on the immediate benefits of behaviour may be optimal during the early stages of behaviour change” but can be reduced as individuals become more intrinsically motivated and confident [73]. What perhaps happened here, is those patients who fizzled out were still at their “early stage” and, as such, required more engagement to keep moving forward. This finding suggests a need to better calibrate coherence when implementing digital health solutions with diverse user groups over time. Future studies should also probe on how variation in degree of goals specification found in this study may also influence patients at different stages of behaviour change. Strengths, limitations, and future research

Like similar studies of digital health interventions in primary care [74], both site and patient recruitment challenges were experienced. Additionally, some values in sample size calculation, like attrition, ended up being underestimated. Underpowering meant all confounding variables collected via demographic baseline surveys and chart reviews could not be included in modeling. Additionally, some context data (notably participation in chronic disease management programs) may have changed over time and was only collected once at baseline. The smaller than anticipated sample size did allow for a more robust approach to ethnographic data collection, resulting in rich qualitative data set which is a strength of the study. Future studies in primary care settings should consider both the setting context and the nature of the intervention being tested to better align the trial methods to real-world implementation. More flexible adaptive trials or applying an interrupted time-series within the clusters may be more appropriate in these dynamic environments. Also worth further exploration is the reason behind why some providers were more successful at identifying eligible patients as compared to others in the study.

Findings may not be widely generalizable to older adults with complex needs as patients in this study were generally a healthier and more educated group. However, the high proportion of complex older women living in rural environments in this project addresses a noted gap in the evidence on interventions for this population [75, 76]. Relying on provider screening may have led to a selection bias which can reduce generalizability. However, as there is a lack of agreed

upon definition of patient complexity, reliance on physician expertise and self-identification has been found to be a viable approach to identify this patient population [77].

Another important limitation to note is this study is missing additional data on provider characteristics, such as age, years of experience and employment status (e.g. full-time or part-time). While a baseline demographic survey was deployed to all providers few remitted these surveys despite multiple attempts to collect the data either via email, phone or in person. While some key variables, such as comfort with technology, were collected via interviews, the other demographic variables would have aided in interpreting data and supported generalizability to other similar provider groups.

While this study offers a multi-method view of the effectiveness of the ePRO tool, findings presented here focus on more major themes that emerged in the analysis. Further analyses will explore the interrelationships between NPT constructs and other context variables, in particular how these concepts relate to professional identities, organizational culture and notions of how best to engage in chronic disease management. An important lesson from this trial is how the nature of GOC and chronic disease management in primary care settings is a fluid and complex process, which are often unique to particular settings and even provider-patient pairs. Highly adaptive trial designs, which allows the study to align to these contexts more closely may have greater success at engagement over these longer trials.

Conclusion

Although the presented study is unable to provide a definitive answer to the effectiveness of the ePRO tool, it did generate novel insights with regard to implementation of digital health technologies in primary care settings. Findings demonstrate the critical role of coherence, or meaningfulness, of an intervention, and the great challenge of aligning coherence across diverse user groups over time. Future work in this space should pay careful attention to how chronic disease management, GOC and self-management are understood and pursued when implementing digital health technologies to advance these models of care.

Acknowledgements

Funding support for this project came from Canadian Institutes of Health Research eHealth Innovation Partnership Program operating grant (FN-143559). The co-authors would like to acknowledge and thank the providers, administrators, and patients who participated in this study. Each of you gave your time, enthusiasm, and energy for which we are deeply grateful. We would also like to thank and acknowledge research support from Jasvinei Srinatharan, Tujuanna Austin, Karen Paik, Candis LePage, Janelle Gravesande, Zaki Hyatt-Shaw, and Parminder Hans for their coordination support throughout this study. We also acknowledge the contribution of collaborators Dr. Cheryl Cott and Dr. Renee Lyons who offered early guidance in this work.

Conflicts of Interest

Funding for this study is through a Canadian Federal Grant (CIHR, FN-143559) with most co-authors salaries being funded through their academic and scientific positions at their respective institutions. One co-author, Sarah Harvey, is the co-founder and co-owner of the technology company that hosts the ePRO tool (QoC Health Inc.). While QoC Health Inc owns the platform on which the ePRO tool sits, the tool itself is intellectual property of the lead author in partnership with the Health System Performance Network at the University of Toronto, which is

led by Dr. Walter Wodchis. Any future aims to commercialize the ePRO tool would be done on the foundation of building a research-supporting not-for-profit that would seek to advance development and evaluation of technologies that support care delivery for patients with complex care needs.

Supplementary Files

Supplement A: data collection schedule

Abbreviations

AFHTO: Association of Family Health Teams of Ontario

AQoL-4D: Assessment of Quality of Life – 4 dimensions

CIHR: Canadian Institutes of Health Research

eHIPP: eHealth Innovation Partnership Program

EMR: Electronic Medical Record

ePRO: electronic Patient Reported Outcomes

FHT: Family Health Team

GOC: Goal-oriented Care

GPs: General Practitioners

NPs: Nurse Practitioners

NPT: Normalization Process Theory

PAM-13: Patient Activation Measure – 13 item

RD: Registered Dietitian

RN: Registered Nurse

SMART: specific, measurable, attainable, realistic, timely

References

1. Hajat, C. and E. Stein, *The global burden of multiple chronic conditions: A narrative review*. Preventive Medicine Reports, 2018. **12**: p. 284-293.
2. Dobrow, M., *Caring for people with chronic conditions: a health system perspective*. International Journal of Integrated Care, 2009. **9**(1).
3. Grindrod, K.A., M. Li, and A. Gates, *Evaluating User Perceptions of Mobile Medication Management Applications With Older Adults: A Usability Study*. JMIR Mhealth Uhealth, 2014. **2**(1): p. e11.
4. Sakaguchi-Tang, D.K., et al., *Patient Portal Use and Experience Among Older Adults: Systematic Review*. JMIR Med Inform, 2017. **5**(4): p. e38.
5. Berntsen, G., et al., *The Evidence Base for an Ideal Care Pathway for Frail Multimorbid Elderly: Combined Scoping and Systematic Intervention Review*. J Med Internet Res, 2019. **21**(4): p. e12517.
6. Matthew-Maich, N., et al., *Designing, Implementing, and Evaluating Mobile Health Technologies for Managing Chronic Conditions in Older Adults: A Scoping Review*. JMIR mHealth uHealth, 2016. **4**(2): p. e29.
7. Evangelista, L., S.R. Steinhubl, and E.J. Topol, *Digital health care for older adults*. The Lancet, 2019. **393**(10180): p. 1493.
8. Herzer, K.R. and P.J. Pronovost, *Ensuring Quality in the Era of Virtual Care*. JAMA, 2021. **325**(5): p. 429-430.

9. Chehade, M.J., et al., *Personal digital health hubs for multiple conditions*. Bulletin of the World Health Organization, 2020. **98**(8): p. 569-575.
10. Sinnott, C., et al., *GPs' perspectives on the management of patients with multimorbidity: systematic review and synthesis of qualitative research*. BMJ Open, 2013. **3**(9): p. e003610.
11. Tinetti, M.E., A.D. Naik, and J.A. Dodson, *Moving From Disease-Centered to Patient Goals-Directed Care for Patients With Multiple Chronic Conditions: Patient Value-Based Care*. JAMA Cardiol, 2016. **1**(1): p. 9-10.
12. Reuben, D.B. and M.E. Tinetti, *Goal-Oriented Patient Care — An Alternative Health Outcomes Paradigm*. New England Journal of Medicine, 2012. **366**(9): p. 777-779.
13. Tinetti, M.E., T.R. Fried, and C.M. Boyd, *Designing health care for the most common chronic condition--multimorbidity*. JAMA, 2012. **307**(23): p. 2493-2494.
14. Schaink, A.K., et al., *A scoping review and thematic classification of patient complexity: Offering a unifying framework*. Journal of Comorbidity, 2012. **2**(1): p. 1-9.
15. World Health Organization. Regional Office of the Western Pacific, *People-centred health care : a policy framework*. 2007: Manila.
16. Coulter, A., et al., *Personalised care planning for adults with chronic or long-term health conditions*. Cochrane Database Syst Rev, 2015. **2015**(3): p. Cd010523.
17. Ahmad, N., et al., *Person-centred care: from ideas to action*. 2014: London, UK.
18. Mold, J.W., G.H. Blake, and L.A. Becker, *Goal-oriented medical care*. Fam Med, 1991. **23**(1): p. 46-51.
19. Secunda, K., et al., *Use and Meaning of @ Goals of Car... in the Healthcare Literature: a Systematic Review and Qualitative Discourse Analysis*. Journal of General Internal Medicine, 2019. **35**: p. 1559-1566.
20. Bisognano, M. and D. Schummers, *Flipping healthcare: an essay by Maureen Bisognano and Dan Schummers*. BMJ : British Medical Journal, 2014. **349**: p. g5852.
21. Schellinger, S.E., et al., *Patient Self-Defined Goals: Essentials of Person-Centered Care for Serious Illness*. Am J Hosp Palliat Care, 2018. **35**(1): p. 159-165.
22. Tinetti, M.E., et al., *Association of Patient Priorities—Aligned Decision-Making With Patient Outcomes and Ambulatory Health Care Burden Among Older Adults With Multiple Chronic Conditions: A Nonrandomized Clinical Trial*. JAMA Internal Medicine, 2019. **179**(12): p. 1688-1697.
23. Berntsen, G.K.R., et al., *Person-centred, integrated and pro-active care for multi-morbid elderly with advanced care needs: a propensity score-matched controlled trial*. BMC Health Services Research, 2019. **19**(1): p. 682.
24. Dolovich, L., et al., *Combining volunteers and primary care teamwork to support health goals and needs of older adults: a pragmatic randomized controlled trial*. Canadian Medical Association Journal, 2019. **191**(18): p. E491.
25. Pirhonen, L., et al., *Effects of person-centred care on health outcomes—A randomized controlled trial in patients with acute coronary syndrome*. Health Policy, 2017. **121**(2): p. 169-179.
26. Kinmonth, A.L., et al., *Randomised controlled trial of patient centred care of diabetes in general practice: impact on current wellbeing and future disease risk. The Diabetes Care From Diagnosis Research Team*. BMJ (Clinical research ed.), 1998. **317**(7167): p. 1202-1208.

27. Greenhalgh, T. and C. Papoutsis, *Studying complexity in health services research: desperately seeking an overdue paradigm shift*. BMC Medicine, 2018. **16**(1): p. 95.
28. Steele Gray, C. and J. Shaw, *From summative to developmental: Incorporating design-thinking into evaluations of complex interventions*. Journal of Integrated Care, 2019. **27**(3): p. 241-248.
29. Steele Gray, C., et al., *Tying eHealth Tools to Patient Needs: Exploring the Use of eHealth for Community-Dwelling Patients With Complex Chronic Disease and Disability*. JMIR Res Protoc, 2014. **3**(4): p. e67.
30. Steele Gray, C., et al., *Improving patient experience and primary care quality for patients with complex chronic disease using the Electronic Patient-Reported Outcomes tool: Adopting qualitative methods into a user-centered design approach*. JMIR Research Protocols, 2016. **5**(1).
31. Steele Gray, C., et al., *The Electronic Patient Reported Outcome Tool: Testing Usability and Feasibility of a Mobile App and Portal to Support Care for Patients With Complex Chronic Disease and Disability in Primary Care Settings*. JMIR Mhealth Uhealth, 2016. **4**(2): p. e58.
32. Steele Gray, C., et al., *Using Exploratory Trials to Identify Relevant Contexts and Mechanisms in Complex Electronic Health Interventions: Evaluating the Electronic Patient-Reported Outcome Tool*. JMIR Form Res, 2019. **3**(1): p. e11950.
33. Tsoukas, H., *Don't Simplify, Complexify: From Disjunctive to Conjunctive Theorizing in Organization and Management Studies*. Journal of Management Studies, 2017. **54**(2): p. 132-153.
34. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance*. BMJ, 2008. **337**: p. a1655.
35. Patton, M., *Utilization-focused evaluation*. 2008, Thousand Oaks, CA: Sage.
36. Hemming, K., et al., *The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting*. BMJ : British Medical Journal, 2015. **350**: p. h391.
37. Hemming, K. and M. Taljaard, *Reflection on modern methods: when is a stepped-wedge cluster randomized trial a good study design choice?* Int J Epidemiol, 2020. **49**(3): p. 1043-1052.
38. Ford, I. and J. Norrie, *Pragmatic Trials*. New England Journal of Medicine, 2016. **375**(5): p. 454-463.
39. Greenhalgh, T. and D. Swinglehurst, *Studying technology use as social practice: the untapped potential of ethnography*. BMC Med, 2011. **9**: p. 45.
40. Steele Gray, C., et al. *Getting to Goals: Using the Electronic Patient Reported Outcome (ePRO) Mobile App to support complex patients in primary care settings*. in *Canadian Association of Health Services and Policy Research*. 2016. Toronto, Ontario.
41. Steele Gray, C., et al., *Supporting Goal-Oriented Primary Health Care for Seniors with Complex Care Needs Using Mobile Technology: Evaluation and Implementation of the Health System Performance Research Network, Bridgepoint Electronic Patient Reported Outcome Tool* JMIR Res Protoc, 2016. **5**(2): p. e126.
42. Glazier, R.H. and D.A. Redelmeier, *Building the patient-centered medical home in Ontario*. Jama, 2010. **303**(21): p. 2186-7.
43. Statistics Canada. *Focus on Geography Series, 2016 Census*. 2016 [cited 2020 September 10 2020]; Available from: <https://www12.statcan.gc.ca/census-recensement/2016/as-sa/fogs-spg/Index-eng.cfm>.

44. Hawthorne, G., S. Korn, and J. Richardson, *Population norms for the AQoL derived from the 2007 Australian National Survey of Mental Health and Wellbeing*. Aust N Z J Public Health, 2013. **37**(1): p. 7-16.
45. Osborne, R., et al., *Quality of life assessment in the community-dwelling elderly: Validation of the Assessment of Quality of Life (AQoL) Instrument and comparison with the SF-36*. Journal of Clinical Epidemiology, 2003. **56**(2): p. 138-147.
46. The Change Foundation. *Partners Advancing Transitions in Healthcare (Path): Northumberland*. 2020; Available from: <https://changefoundation.ca/path-northumberland/>.
47. Centre for Health Economics. *Assessment of Quality of Life*. 2020 [cited 2020 December 3 2020]; Available from: <http://aqol.com.au/index.php/aqolinstruments>.
48. Hibbard, J.H., et al., *Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers*. Health services research, 2004. **39**(4 Pt 1): p. 1005-1026.
49. Skolasky, R.L., et al., *Psychometric properties of the patient activation measure among multimorbid older adults*. Health services research, 2011. **46**(2): p. 457-478.
50. Hibbard, J.H., et al., *Development and testing of a short form of the patient activation measure*. Health services research, 2005. **40**(6 Pt 1): p. 1918-1930.
51. Bradway, M., et al., *Analysing mHealth usage logs in RCTs: Explaining participants' interactions with type 2 diabetes self-management tools*. PLoS One, 2018. **13**(8): p. e0203202.
52. Davey, C., et al., *Analysis and reporting of stepped wedge randomised controlled trials: synthesis and critical appraisal of published studies, 2010 to 2014*. Trials, 2015. **16**: p. 358.
53. Sandelowski, M., *Whatever happened to qualitative description?* Research in Nursing & Health, 2000. **23**(4): p. 334-340.
54. Sandelowski, M., *Telling stories: narrative approaches in qualitative research*. Image J Nurs Sch, 1991. **23**(3): p. 161-6.
55. Gale, N.K., et al., *Using the framework method for the analysis of qualitative data in multi-disciplinary health research*. BMC Medical Research Methodology, 2013. **13**(1): p. 117.
56. Cresswell, J.W. and C.N. Poth, *Qualitative Inquiry & Research Design: Choosing among five approaches*. 4th ed. 2018, Thousand Oaks, CA: Sage Publications Inc.
57. Cresswell, K. and A. Sheikh, *Organizational issues in the implementation and adoption of health information technology innovations: an interpretative review*. International journal of medical informatics, 2013. **82**(5): p. e73-e86.
58. Salisbury, C., et al., *Management of multimorbidity using a patient-centred care model: a pragmatic cluster-randomised trial of the 3D approach*. The Lancet, 2018. **392**(10141): p. 41-50.
59. Tracy, C.S., et al., *The IMPACT clinic: innovative model of interprofessional primary care for elderly patients with complex health care needs*. Can Fam Physician, 2013. **59**(3): p. e148-55.
60. Ploeg, J., et al., *Managing multiple chronic conditions in the community: a Canadian qualitative study of the experiences of older adults, family caregivers and healthcare providers*. BMC geriatrics, 2017. **17**(1): p. 40-40.

61. Harrison, C., et al., *Examining different measures of multimorbidity, using a large prospective cross-sectional study in Australian general practice*. *BMJ Open*, 2014. **4**(7): p. e004694.
62. Hawthorne, G., J. Richardson, and N. Day, *Using the Assessment of Quality of Life (AQoL) Version 1*, in *Technical Report 12*. 2009: Australia.
63. May, C.R., et al., *Development of a theory of implementation and integration: Normalization Process Theory*. *Implementation Science*, 2009. **4**(1): p. 29.
64. Fernandez-Lazaro, C.I., et al., *Adherence to treatment and related factors among patients with chronic conditions in primary care: a cross-sectional study*. *BMC Family Practice*, 2019. **20**(1): p. 132.
65. Osterberg, L. and T. Blaschke, *Adherence to Medication*. *New England Journal of Medicine*, 2005. **353**(5): p. 487-497.
66. Donkin, L., et al., *A Systematic Review of the Impact of Adherence on the Effectiveness of e-Therapies*. *J Med Internet Res*, 2011. **13**(3): p. e52.
67. Manwaring, J.L., et al., *Do adherence variables predict outcome in an online program for the prevention of eating disorders?* *J Consult Clin Psychol*, 2008. **76**(2): p. 341-6.
68. Perski, O., et al., *Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis*. *Transl Behav Med*, 2017. **7**(2): p. 254-267.
69. Lee, K., et al., *Effect of self-monitoring on long-term patient engagement with mobile health applications*. *PloS one*, 2018. **13**(7): p. e0201166-e0201166.
70. Ziemer, D.C., et al., *An Intervention to Overcome Clinical Inertia and Improve Diabetes Mellitus Control in a Primary Care Setting: Improving Primary Care of African Americans With Diabetes (IPCAAD) 8*. *Archives of Internal Medicine*, 2006. **166**(5): p. 507-513.
71. Steele Gray, C., *Seeking Meaningful Innovation: Lessons Learned Developing, Evaluating, and Implementing the Electronic Patient-Reported Outcome Tool*. *J Med Internet Res*, 2020. **22**(7): p. e17987.
72. Bodenheimer, T., et al., *Patient Self-management of Chronic Disease in Primary Care*. *JAMA*, 2002. **288**(19): p. 2469-2475.
73. Morrison, L.G., *Theory-based strategies for enhancing the impact and usage of digital health behaviour change interventions: A review*. *DIGITAL HEALTH*, 2015. **1**: p. 2055207615595335.
74. O'Connor, S., et al., *Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies*. *BMC Medical Informatics and Decision Making*, 2016. **16**(1): p. 120.
75. Liu, K.A. and N.A.D. Mager, *Women's involvement in clinical trials: historical perspective and future implications*. *Pharmacy practice*, 2016. **14**(1): p. 708-708.
76. Virani, S., et al., *Barriers to recruitment of rural patients in cancer clinical trials*. *Journal of oncology practice*, 2011. **7**(3): p. 172-177.
77. Grant, R.W., et al., *Defining Patient Complexity From the Primary Care Physician's Perspective*. *Annals of Internal Medicine*, 2011. **155**(12): p. 797-804.