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The Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC): Preliminary development and protocol for item selection, calibration and validation.

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The Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC): Preliminary development and protocol for item selection, calibration and validation.

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ABSTRACT

Introduction: Assessing and measuring patients' chronic condition self-management needs is critical to quality health care and to related research. One in three adults around the world live with multiple chronic conditions. While many patient-reported measures of self-management have been developed, none has emerged as the gold standard, and all have one or more of the following limitations: 1) they fail to measure the domains of self-management important to patients; 2) they lack sufficient specificity to support patient-centred care or identify the specific components of self-management interventions that work; and/or 3) they lack suitability for patients with multi-morbidity.

Methods and analysis: The Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC) is being developed to overcome these shortcomings. It will measure respondents' perceived success (or difficulty) in self-managing seven domains important to patients. The protocol has three phases. Phase 1 is conceptual model development and item generation. Phase 2 is assessing the relevance and understanding of items by people with chronic conditions. Phase 3 is item analysis, dimensionality assessment, scaling and preliminary validation of the PRISM-CC using an online survey of people with chronic conditions (n~750). The expected completion date is late 2020.

Ethics and dissemination: This study will adhere to the Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. Phase 1 was conceptual, hence did not require ethics approval. Phase 2 was approved, and approval for Phase 3 is pending, by the Nova Scotia Health Authority Research Ethics Board. Once completed, the PRISM-CC will be made available for research and health care at minimal to no cost.

KEYWORDS

Patient reported outcome measure; self-management; chronic disease management; multimorbidity

ARTICLE SUMMARY

Strengths and limitations of this study

- The Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC) will measure self-perceived difficulty managing the multiple domains of self-management.
- It will use a conceptual framework that includes domains of relevance to patient experiences and enables health providers to assess needs and provide care.
- It will enable researchers to isolate and study critical ingredients of self-management programs.
- It will be designed and validated for patients with multi-morbidity.
- The calibration will be based on a sample of convenience and may be limited by the diversity of the sample recruited.

INTRODUCTION

Globally, approximately one in three adults live with multiple chronic conditions.(1) Chronic condition management, and patient “self-management” in particular, are a major focus of health services policy, redesign and research.(2, 3) Self-management is defined by the Institute of Medicine as the “tasks that individuals must undertake to live well with one or more chronic conditions”,(4) and includes the daily actions people do and do not take to successfully manage their chronic conditions.(5) It includes making decisions, taking action and altering behaviours in the context of living every day.(6, 7) Learning to self-manage is not a one-time event. It is a lifelong process, because chronic conditions, and life itself, fluctuate and change over time.(8–11)

Assessing and measuring patients’ difficulty self-managing their condition(s) is thus critical to quality health care and related research. While many patient-reported measures of self-management have been developed, none has emerged as the gold standard, and all have major limitations: 1) failure to measure the domains of self-management important to patients; 2) lack of sufficient specificity to support patient-centred care or identify the specific components of self-management interventions that work; and 3) lack of suitability for patients with multi-morbidity.

Failure to measure the domains of self-management important to patients: Extensive qualitative research on patient self-management, including a number of rigorous reviews, demonstrate that self-management is multi-dimensional consisting of different skills, abilities and attitudes, and covering multiple aspects of living everyday life with a chronic condition.(12–18) Yet, a scoping review, conducted to understand how self-management is measured found that 15 of 28 included self-management measures are unidimensional, providing only a single score.(19) While statistical evidence for the unidimensionality of some measures is documented,(20–22) this may result from limiting focus to one domain of self-management,(23) or from the use of insufficient statistical criteria such as principle components analysis or exploratory factor analysis.(24) Other measures, such as the Partners in Health Scale, provide a single composite score, but the statistics demonstrate strong evidence of underlying

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3 multidimensionality.(23, 25, 26) While the scoping review found that 13 of the 28 measures
4 were multidimensional, none of them captured the range of domains identified by the *Taxonomy*
5 *of Everyday Self-Management Strategies* (TEDSS), a comprehensive set of self-management
6 domains important to patients.(27)
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12 ***Lack of sufficient specificity for individualized patient care and self-management research:***

13 Single-score measures can be brief, reliable and valid instruments for screening, risk prediction
14 and for use in outcome studies,(28) but they have limited utility for differentiating individual
15 patients' self-management support needs or in personalizing or tailoring care. A Cochrane
16 review (19 studies n=10,856 participants) concluded that when compared to usual care,
17 personalized care planning leads to improvements in “physical and psychological health status,
18 and peoples' capacity to self-manage their condition”.(29) Measures that differentiate self-
19 management into separate domains are needed to move beyond “one size fits all” interventions
20 that are responsive to patients' diverse and changing needs over the disease trajectory. Research
21 to isolate the critical ingredients of self-management interventions also depend on the ability to
22 differentiate and measure each self-management domain.
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32 ***Suitability for patients with multi-morbidity:*** A growing percentage of patients experience
33 multi-morbidity, yet condition-specific measures of self-management are most common. Of the
34 28 measures identified in the scoping review, 20 were specific to a particular condition.(19)
35 While disease specific measures clearly play an important role in care and research, there is a
36 growing need for measures of self-management appropriate for patients with multi-morbidity
37 and complex needs. The prevalence of multi-morbidity is increasing, and nonmedical aspects of
38 complex needs such as mental illness and social isolation combined with social determinants of
39 health such as low socioeconomic status, have large effects on patients' ability to self-
40 manage.(30) Multi-morbidity also makes self-management more difficult for patients.(10, 12, 31,
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51 In addition to addressing the above limitations, measures of self-management are needed that can
52 be routinely used, in diverse settings, with minimal to no cost. Licensing costs pose practical
53 barriers to routine use. For use in clinical care, measures must be efficient to administer, yet
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3 provide sufficient detail to support individualized care. There is a practical trade-off between
4 multidimensional measures that have higher response burden and are more time-consuming to
5 administer, and shorter, unidimensional scales that lack meaningful detail. Innovations in
6 measurement, such as computer adaptive testing, using well calibrated items, can minimize
7 response burden for patients while providing information on multiple domains.(33)
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13 This paper describes the protocol for development of a new measure of perceived success (or
14 difficulty) in self-management: the Patient Reported Inventory of Self-Management of Chronic
15 Conditions (PRISM-CC). The PRISM-CC aims to address the limitations of current self-
16 management measures. A conceptual framework that includes domains of relevance to patient
17 experiences forms the foundation, enabling health providers to assess needs and provide
18 individualized care. PRISM-CC will enable researchers to isolate and test critical ingredients of
19 self-management programs. It will be designed and validated for patients with multi-morbidities;
20 although, we expect that it's utility will extend beyond this population.
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28 29 30 31 **METHODS AND ANALYSIS**

32 Development of the PRISM-CC will follow the *PROMIS® Instrument Development and*
33 *Validation Scientific Standard, Version 2.0.*(34) This paper first describes the preliminary
34 development of the PRISM-CC (Phases 1 and 2) then outlines the protocol for the final study
35 (Phase 3). Phase 1 was completed in the fall of 2018 by generating a bank of potential items
36 from existing measures and available qualitative data material (Figure 1). During Phase 2,
37 completed in fall 2019, items were tested in an online survey (n=40 persons with multiple
38 chronic conditions), followed by cognitive interviews to select potential items for further testing.
39 In Phase 3, the bank of potential items will be administered to a large and diverse sample of
40 persons with chronic conditions (N~750) between January and July 2020. Item analysis,
41 dimensionality assessment, scaling and preliminary validation of the PRISM-CC will then be
42 conducted. The expected completion date is late 2020.
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52 In developing a patient reported outcome measure, inclusion of “patients”, both as participants
53 and research partners is an important. Patient perspectives and involvement have, and will
54 continue to be an integral part of development of the PRISM-CC. Two members of the research
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3 team are ‘patient-partners’ (community members, each living with multi-morbidity and/or
4 complex chronic health conditions), and members of the research team live with multi-morbidity.
5 These team members have and will continue to be involved in project planning and key decision-
6 making meetings. For example, during Phase 1 and 2, patient-partner team members aided in the
7 development and refinement of the items, provided feedback on the design and usability of the
8 first online survey, and facilitated participant recruitment. Their continued input will be sought
9 throughout the development of PRISM-CC, including the calibration study, format of the final
10 PRISM-CC outcome measure and project dissemination. Additionally, patient participants with
11 chronic conditions provided original data to inform PRISM-CC item development through
12 survey and cognitive interviewing processes. Further data collection from patient participants
13 will play an important role during Phase 3.
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24 *PUT FIGURE 1 ABOUT HERE: Flow Diagram for the Development of the Patient*
25 *Reported Inventory of Self-Management for patients with Chronic Conditions (PRISM-*
26 *CC)*
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31 **Phase 1: Generate potential items for each domain in our conceptual framework**

32 **(completed)**

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34 Due to its comprehensiveness, recency, and applicability to patients with multiple conditions, the
35 **Taxonomy of Every Day Self-management Strategies (TEDSS)**, a conceptual framework which
36 describes the everyday strategies people use to live with and manage their conditions was chosen
37 to guide development of the PRISM-CC.(27) It was developed using concept mapping
38 methodology,(35) then refined and validated using original data from individuals with one or
39 more neurological conditions. First, data from 77 research papers (n=41 qualitative and n=36
40 quantitative) were analyzed in order to clarify the overlapping concepts of coping, adapting and
41 self-managing a neurological condition.(14) Framework domains (n=7) and subdomains (n=25)
42 were then refined and validated using original data (7,236 statements) from repeated, structured
43 interviews with 117 individuals with neurological conditions over an eleven month period.(36)
44 Individuals with neurological conditions vary widely by age of onset, trajectory and impact;
45 motor, perceptual, cognitive and psychological symptoms exist in variable combinations,
46 providing a strong foundation for the TEDSS addressing the issues of individuals with multiple
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conditions. Finally, the framework was compared to three additional conceptual frameworks reported in the literature to confirm applicability beyond neurological conditions.(7, 12, 37) PRISM-CC will measure respondents' perceived success (or difficulty) in self-managing each TEDSS domain. TEDSS is a typology of strategies, thus its domain definitions were reframed into working PRISM-CC definitions, as shown in Table 1.

Table 1: Domains in the Taxonomy of Everyday Self-management Strategies, and Associated Working Definitions used by PRISM-CC

Domain	TEDSS Definition	PRISM-CC Working Definition
Process Strategies	Strategies used to be well informed and to make good decisions. Often used to support use of other, non-process strategies.	Self-perceived success at seeking information, being aware of choices and making good decisions.
Resource Strategies	Proactively seeking, pursuing and/or managing needed formal or informal supports and resources.	Self-perceived success at seeking, pursuing and/or managing needed formal or informal supports and resources.
Activities Strategies	Finding ways to participate in everyday activities (leisure activities, work activities, household chores) despite problems such as fatigue, pain, memory loss or disability.	Self-perceived success at creating inner calm by preventing and managing stress, negative emotions and internal distress.
Internal Strategies	Preventing and managing stress, negative emotions and internal distress; creating inner calm.	Self-perceived success in participating in everyday activities (leisure activities, work activities, household chores).
Social Interaction Strategies	Managing social interactions and relationships to be able to participate without exposure to negative reactions.	Self-perceived success at disclosing health issues, managing social interactions and relationships.
Health Behaviour Strategies	Maintaining a healthy lifestyle in order to enhance health and limit the risk of lifestyle related illness.	Self-perceived success at maintaining a healthy lifestyle.

Disease Controlling Strategies	Preventing, controlling and limiting symptoms, complications and/or disease progression.	Self-perceived success at managing a health condition(s) including managing medications and treatments, monitoring symptoms, and limiting complications.
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Potential items for each domain in the PRISM-CC were first drawn from outcome measures identified in the scoping review of self-management outcome measures.⁽¹⁹⁾ The context (instructions associated with answering the question), the item, and any stem (initial phrase of the item, repeated across items), response options, recall period, and origin of items were tabulated. Additional items were generated using qualitative data previously collected in Canada to develop and validate the TEDSS framework,⁽³⁶⁾ and by members of the research team. Grounding items in real-life examples is expected to increase face validity.

The research team reviewed 250 potential items using an iterative process that included assessment of face validity, coherence, relevance and patient-centred wording. No fewer than three research team members participated in the assessment of items in each domain. Based on consensus, items were eliminated if 1) they did not conceptually fit a domain 2) were semantically identical/redundant, 3) the content was too narrow or disease-specific to be applicable to patients with multi-morbidity, or 4) the item did not assess patient perception of success or difficulty in self-managing. Item stems and response scales were developed to meet PROMIS standards and recommendations (e.g. preferred response set options, time reference, context).⁽³⁴⁾ A total of 30-35 items per domain (n=231) were selected for assessment or relevance and understanding for persons with multiple chronic conditions.

Phase 2: Assess potential items for relevance and understanding to people with multiple chronic conditions; generate preliminary item bank (completed).

Online Survey #1: People (n=40) with two or more chronic conditions were recruited to complete an online survey of potential items (n=231). The purposive sample was recruited via: posters displayed in public areas and health care settings; newsletters and distribution lists; and

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3 social media. Participants had to be able to read/speak English and have self-reported diagnosis
4 of ≥ 2 chronic conditions. Interested participants first underwent a screening telephone interview
5 to assess inclusion criteria and gather data needed to achieve maximum variation: age (younger
6 or older than age 50); gender identity (man, woman, or other); high school completion (yes or
7 no); and number of diagnoses and time since diagnoses. The first 20 eligible participants were
8 invited to participate. Subsequent recruitment, using the same methods, was purposive, filling
9 gaps to achieve maximum variation in overall participant profiles.

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12 Surveys were administered using an anonymous online survey platform housed on a Canadian
13 University server. To reduce participant burden, the item pool (total $n=231$) was divided in half,
14 with each participant rating only 50% of the items. Participants were asked to complete each
15 potential item using a 5-point response scale. They also rated each item for difficulty and
16 importance using a 10-point rating scale.

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19 Item analysis was conducted based on item responses and answers to questions assessing
20 difficulty and importance. Given the small sample size, analyses were considered indicative only
21 and used to flag extremely poorly fitting items and those requiring cognitive interviewing.
22 Response distributions provided evidence of potential floor and ceiling affects, while poor item-
23 rest correlations identified items likely to have poor fit to the domain, or that appeared to be
24 interpreted differently than expected. Exploratory factor was used, with caution given the small
25 sample size, to provide insight into item groupings within domains where many item-rest
26 correlations were weak. Low mean scores on importance and/or high scores on difficulty
27 provided insight into respondents' views on importance and ease of understanding.
28 Items which performed well on all aspects of the item analysis and were consistently evaluated
29 as easy to understand and important to respondents, were carried forward to Phase 3. Items
30 which showed inconsistency in understandability or importance, or which performed moderately
31 well in the item analysis, were carried forward to the cognitive interviews. Those with overall
32 poor performance were removed from the item bank.

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53 **Face to Face Cognitive Interviews:** A subsample of survey participants ($n=10$) were invited,
54 based on availability and maximum variation, to participate in individual cognitive interviews.

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3 Participants met individually with trained research staff to assess a version of the survey with 30
4 to 40 items. This resulted in two to five cognitive interviews per item. One team member
5 conducted the interview, while a second team member took field notes. Interviews were audio-
6 recorded and transcribed verbatim.
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11 Each item was first scored by the participant. This was followed by an interview using “think-
12 aloud” methodology which invited participants to describe how they interpreted it and selected
13 their response.(38, 39) Participants were also asked how alternative instructions or response
14 scales might change their interpretation and/or answer. Finally, participants were asked about the
15 importance and difficulty of items using questions such as *You circled “x” as your response to*
16 *the question asking about the importance of this item. Please tell me what things you were*
17 *thinking about when answering this question.*
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25 Text was tabulated by item and analysed to provide insight into interpretation and acceptability
26 of item stems, response scales, and patient oriented language. Specific words or terms found to
27 be unclear, easily misunderstood, or judgemental were flagged for application across all items.
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32 ***Generation of Preliminary Item Bank:*** Using findings from the online survey and cognitive
33 interviewing data, each item was assessed for domain coherence, clarity, and understandability.
34 Whether the item measured perceived success or difficulty in self-management and its potential
35 scalability were also considered. To ensure consistent assessment, the first 20 items were
36 reviewed by the full research team and all other items were assessed by a minimum of two team
37 members. All potential items were assessed for semantic similarity with only the most promising
38 one or two items per group retained. Finally, overall face and content validity of each domain
39 was assessed by ensuring coherence between items and domain definitions. These items (N=105)
40 form the preliminary PRISM-CC item bank for testing in Phase 3.
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50 **Phase 3: Protocol to select and calibrate the final PRISM-CC items in a sample of people**
51 **with chronic conditions and to conduct preliminary validation (to be completed).**
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Participants: Participants will be recruited using the following inclusion criteria: age 18 years of age or older, able to read/speak English, and self-reported diagnoses of ≥ 1 chronic condition.

Multiple strategies will be used to recruit participants:

1. Posters displayed in public areas, including health care settings,
2. Posters and information distributed to patients attending group/individual sessions,
3. Invitations to participate placed in newsletters and/or via relevant distribution lists, and
4. Social media and free online advertising sites.

All recruitment materials will include the URL to the survey; participants will not be required to contact the research team nor to enter information such as name, address, or health card numbers. Simulations on PROMIS data, based on similar item development methods, show that as few as 250 subjects are sufficient for this analyses.⁽⁴⁰⁾ However, sample size calculations for confirmatory factor analysis were also performed to inform the needed sample size.^(41, 42) Assuming 80% power to differentiate good vs moderate fit (RMSEA of .04 vs .06) in the most complex model: a fully stratified (2-5 groups) non-orthogonal model including mean structures (substantially similar to IRT), with seven domains and a minimum of 4-7 items per domain, a sample size of 587 was determined. We will recruit 750 participants to compensate for loss of power due to non-normality and unequal numbers between groups.

Online Survey: When potential participants access the public URL to the online survey, the landing page will include the purpose, inclusion criteria, what participants will be asked to do and information regarding confidentiality and anonymity, compensation and who to contact in case of questions or concerns. Participants will consent by answering 'yes' to the question "Do you wish to participate in this survey?" The first questions of the survey will be used to confirm eligibility, and those not eligible will receive a thank you message with no further questions asked. The remainder of the survey will consist of 105 potential PRISM-CC items (15-17 items per domain), 10 socio-demographic questions (age, gender identity, country of residence, current living situation, first language, education, types of chronic conditions, status of general health, status of general mental health, and impact of chronic condition(s) on life), and a six-item validated self-management tool, the Self-Efficacy for Managing Chronic Disease Scale (SEMCD).⁽⁴³⁾ Based on the Phase 2 survey, 20 - 30 seconds per item is a reasonable expectation

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3 resulting in a total time of 40 minutes to 1.0 hour to complete the survey. Participants will have
4 the option to leave the survey at any time, returning to complete it later.
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8 At the end of the survey, participants will have the opportunity to enter their name and email
9 address for a chance to win one of four \$100.00 gift cards. This will be collected in a second,
10 unconnected survey and will be used only to select winners of the gift cards.
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15 ***Dimensionality and Calibration Analysis:*** Stages of analysis will include item analysis,
16 assessment of dimensionality, and calibration.(34, 44) Analysis will be done in Stata and R
17 (packages ltm and MultiLCIRT). Item analysis will be used to identify and exclude items that are
18 highly skewed, lack variance, or are weakly correlated with other items in their domain.
19 The structural validity of the items against our conceptual model will be empirically tested.
20 Given the strong conceptual model and qualitative validation, confirmatory factor analysis
21 (CFA) will evaluate whether the data fits our seven-domain conceptual framework (including
22 any revisions).(45, 46) Fit will be assessed using multiple indices (e.g. Comparative Fit Index,
23 Tucker Lewis Index, RMSEA and SRMR).(46) A joint model will estimate the correlation
24 between domains. CFA will also be used to help determine if any domain should be collapsed
25 (augmented by results from the qualitative dimensionality assessment described above), and to
26 asses measurement invariance by gender identification, age group, education and health status
27 groups. Modification indices will identify items with high cross loadings across domains. If the
28 CFA for any of the domains show poor fit, exploratory factor analysis will be conducted to
29 explore structural patterns of the items.
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43 Items within each domain will be calibrated with item response theory (IRT).(34) Well
44 calibrated IRT items can be incorporated into computerized adaptive testing to measure
45 constructs using as few as 4-5 items, thus reducing response burden.(47) Assumptions for IRT
46 scaling (local independence and monotonicity of items) will be assessed. Items violating
47 assumptions will be excluded, or further examined in the IRT analysis to determine their
48 influence on parameter estimates. Samejima's Graded Response Model (GRM) will be the
49 preferred modeling approach, but other polytomous IRT models will also be estimated for
50 comparison. (34, 44, 48) The performance of each item/response category will be reviewed using
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category response curves and estimates of item information. Differential item functioning (DIF) analysis will be conducted by age, gender, self-reported health status, extent of multi-morbidity and education. For each domain, we will seek a set of best items that provide reliable estimates across levels of the latent construct, and which do not have differential item functioning.(44, 48)

Preliminary Validation Analysis: Preliminary validity will be assessed by examining known relationships between each TEDSS domain and the generic Self-Efficacy for Managing Chronic Disease Scale (SEMCD), a well-known and highly used outcome measure of confidence to manage a chronic condition.(43) The SEMCD is used in research, clinical, and practice settings to measure self-management. Evidence suggests this tool is a reliable generic measure of self-management with evidence of construct validity.(23)

In addition to the SEMCD, individual TEDSS domains will be validated by examining associations with the known correlates of education, general and mental health (including number of chronic conditions) and/or a measure of impact on everyday life (see Table 2). Level of education (categorical) and number of chronic conditions will be extracted from collected demographic information. Self-reported general and mental health will be assessed using common single item measures from the Canadian Community Health Survey.(49) The impact of the chronic condition will be measured using a single item from the study, Living with the Everyday Impact of a Neurological Condition (the LINC study).(36)

Table 2: Known Relationships by TEDSS Domain.

TEDSS Domain	Known Relationship
Process	Positive relationship with education.(50, 51)
Resources	Positive relationship with education.(52–54)
Disease Management	Inverse relationship with number of conditions.(55, 56)
Health Behaviours	Inverse relationship with general health.(57) Positive relationship with education.(58, 59)
Activities	Inverse relationship with participation in everyday life.(52)
Internal Social Interaction	Positive relationship with mental health.(52, 59) Positive relationship with mental health(52)

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4 Bivariate analysis and multivariate analyses will be conducted to examine relationships between
5 the TEDSS domains and relevant categorical variables (education, general health, mental health,
6 and impact on participation).
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10 11 12 **ETHICS AND DISSEMINATION** 13

14 All procedures will adhere to the Canadian Tri-Council Policy Statement on Ethical Conduct for
15 Research Involving Humans. Phase 1 did not include collection of original data; therefore, ethics
16 approval was not required. Ethics approval for Phase 2 was received from the Nova Scotia
17 Health Authority Research Ethics Review Board. Approval for Phase 3 is pending approval.
18 This study has and will continue to use an integrated knowledge translation approach.(60). Team
19 members include patient-partners, policy makers and managers in primary care. All have and
20 will shape the research process. A summary of our results will be posted on our website,
21 accessible to patients and the public. The Primary Health and Chronic Disease Portfolio in the
22 Nova Scotia is actively using the conceptual framework employed for the PRISM-CC to guide
23 assessment and planning in primary care and chronic disease management, and has provided
24 extensive consultations to our team on the attributes of PRISM-CC that will be required to
25 facilitate its integration into care. To facilitate uptake and use, the final PRISM-CC will be made
26 available for research and clinical care at minimal or no cost.
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46 the PRISM-CC.
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AUTHOR CONTRIBUTIONS

Conceptualisation: TP, GK, AA, and GW. Methodology: TP, GK, AA, GW, KP, and ACK.

Project Administration: TP, GK, KP, and TS. Data Curation: TP, GK, AA, KP, and ACK.

Funding acquisition: TP, GK, AA, TS, GW, and ACK. Methodology: TP, GK, AA, KP, GW, and ACK. Writing, reviewing and editing: all authors.

COMPETING INTERESTS

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DATA STATEMENT

Legend (Title) for Figure 1: Flow Diagram for the Development of the Patient

Reported Inventory of Self-Management for patients with Chronic Conditions (PRISM-CC)

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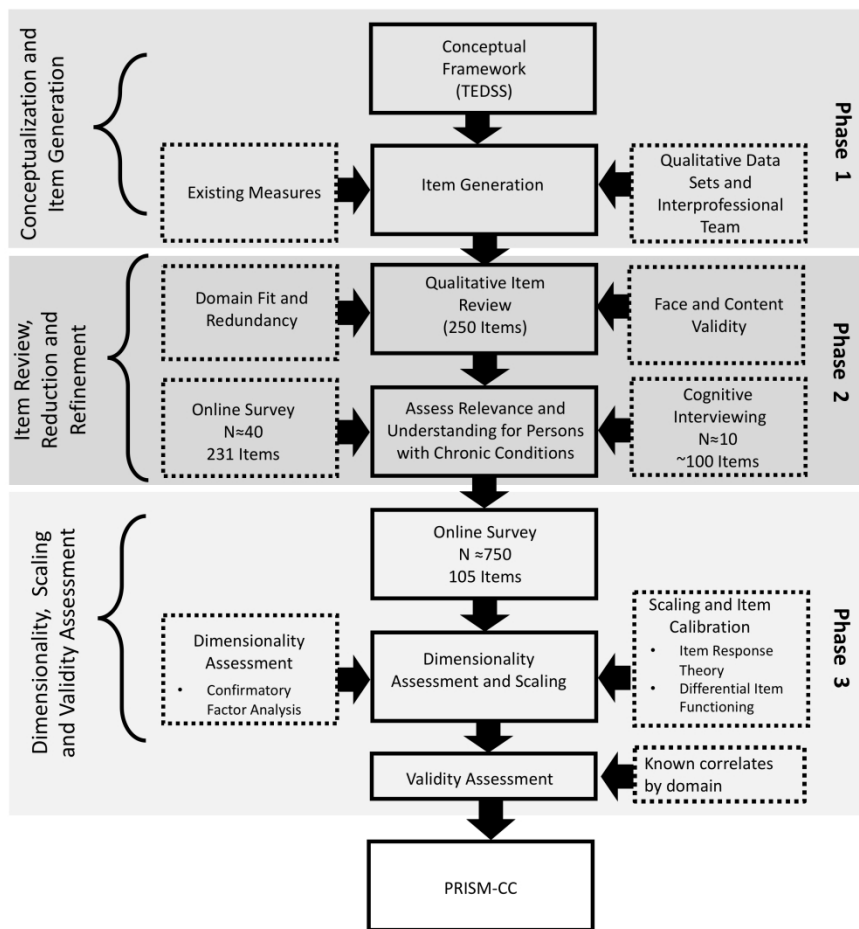


Figure 1: Flow Diagram for the Development of the Patient Reported Outcome Measure for Patients with Chronic Conditions (PRISM-CC)

269x270mm (300 x 300 DPI)

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Protocol for Development, Calibration and Validation of the Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC)

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ABSTRACT

Introduction: Assessing and measuring patients' chronic condition self-management needs is critical to quality health care and to related research. One in three adults around the world live with multiple chronic conditions. While many patient reported measures of self-management have been developed, none has emerged as the gold standard, and all have one or more of the following limitations: 1) they fail to measure the different domains of self-management important to patients; 2) they lack sufficient specificity to support patient-centred care or identify the specific components of self-management interventions that work; and/or 3) they lack suitability for patients with multiple chronic conditions.

Methods and analysis: The Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC) is being developed to overcome these shortcomings. It will measure respondents' perceived success (or difficulty) in self-managing seven domains important to patients. The protocol has three phases. Phase 1 is conceptual model development and item generation. Phase 2 is assessment of the relevance and understanding of items by people with chronic conditions. Phase 3 is item analysis, dimensionality assessment, scaling and preliminary validation of the PRISM-CC using an online survey of people with chronic conditions (n~750). The expected completion date is early 2021.

Ethics and dissemination: This study will adhere to the Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. Ethics approval for all Phases has been obtained from the Nova Scotia Health Authority Research Ethics Board. Once completed, the PRISM-CC will be made available for research and health care at minimal to no cost.

KEYWORDS

Patient reported outcome measure; self-management; chronic disease management; multimorbidity

Strengths and limitations of this study

- PRISM-CC development will be based on a validated conceptual framework that includes seven domains of self-management identified by patients as relevant to their experiences.
- PRISM-CC will be designed and validated for patients with one or more chronic conditions, facilitating broad application in clinical and research settings.
- Items will be calibrated using Item Response Theory models, enabling their use in computer adaptive testing.
- Initial calibration will be based on data collected online from a convenience sample, which may limit diversity and generalizability.
- Additional studies will be required to assess applied construct validity and scale invariance across different populations.

INTRODUCTION

Globally, approximately one in three adults live with multiple chronic conditions.[1] Chronic condition management, and patient “self-management” in particular, are a major focus of health services policy, redesign and research.[2, 3] Self-management is defined by the Institute of Medicine as the “tasks that individuals must undertake to live well with one or more chronic conditions”,[4] and includes the daily actions people do and do not take to successfully manage their chronic conditions.[5] It includes making decisions, taking action and altering behaviours in the context of living every day.[6–8] Learning to self-manage is not a one-time event. It is a lifelong process, because chronic conditions, and life itself, fluctuate and change over time.[8–12]

Assessing and measuring patients’ difficulty self-managing their condition(s) is thus critical to quality health care and related research. While many patient reported measures of self-management have been developed, none has emerged as the gold standard, and all have major limitations: 1) failure to measure the different domains of self-management important to patients; 2) lack of sufficient specificity to support patient-centred care or identify the specific components of self-management interventions that work; and 3) lack of suitability for patients with multiple chronic conditions.

Failure to measure the different domains of self-management important to patients: Extensive qualitative research on patient self-management, including a number of rigorous reviews, demonstrates that self-management consists of different domains, or aspects of self-management, comprising different skills, abilities and attitudes patients use to address the challenges of living everyday life with a chronic condition.[8, 13–19] For example, the **Taxonomy of Every Day Self-Management Strategies (TEDSS)**, has identified seven different domains of self-management important to patients (see Table 1).[20] Yet, a scoping review, conducted to understand the different instruments used to measure self-management found that 15 of 28 included self-management measures are unidimensional, providing only a single score.[21] While statistical evidence for the unidimensionality of some measures is documented,[22–24] this may result from limiting the focus to one domain of self-management,[25] or from the use of

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3 insufficient statistical criteria such as principle components analysis or exploratory factor
4 analysis.[26] Other measures, for example, the Partners in Health Scale, provide a single
5 composite score, but analyses provide strong evidence of underlying multidimensionality.[25,
6 27, 28] While the scoping review found that 13 of the 28 measures were multidimensional, none
7 of them captured the range of domains important to patients, as identified by the TEDSS.[20]
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13 ***Lack of sufficient specificity for individualized patient care and self-management research:***

14 Single-score measures can be brief, reliable and valid instruments for screening, risk prediction
15 and for use in outcome studies,[29] but they have limited utility for differentiating individual
16 patients' self-management support needs or in personalizing or tailoring care. A Cochrane
17 review (19 studies n=10,856 participants) concluded that when compared to usual care,
18 personalized care planning leads to improvements in "physical and psychological health status,
19 and peoples' capacity to self-manage their condition".[30] Measures that differentiate self-
20 management into separate domains are needed to move beyond "one size fits all" interventions
21 that are responsive to patients' diverse and changing needs over their disease trajectories.
22 Research to isolate the critical ingredients of self-management interventions also depends on the
23 ability to differentiate and measure separate domains of self-management.
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34 ***Suitability for patients with multiple chronic conditions:*** A growing percentage of patients
35 experience multiple chronic conditions (i.e. multimorbidity),[1] yet condition-specific measures
36 of self-management are most common. Of the 28 measures identified in the scoping review, 20
37 were specific to a particular condition.[21] While disease specific measures clearly play an
38 important role in care and research, there is a growing need for measures of self-management
39 appropriate for patients with multiple chronic conditions and complex needs. Nonmedical
40 aspects of living with chronic conditions such as social isolation combined with social
41 determinants of health such as low socioeconomic status, have large effects on patients' ability to
42 self-manage.[31] Having multiple chronic conditions also makes self-management more difficult
43 for patients.[11, 13, 32, 33]
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53 In addition to addressing the above limitations, measures of self-management are needed that can
54 be routinely used, in diverse settings, with minimal to no cost. Licensing costs pose practical
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3 barriers to routine use. For use in clinical care, measures must be efficient to administer, yet
4 provide sufficient detail to support individualized care. There is a practical trade-off between
5 multidimensional measures that have higher response burden and are more time-consuming to
6 administer, and shorter, unidimensional scales that lack meaningful detail. Innovations in
7 measurement, such as computer adaptive testing, using well calibrated items, can minimize
8 response burden for patients while providing information on multiple domains.[34]
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15 This paper describes the protocol for development of a new measure of self-management: the
16 Patient Reported Inventory of Self-Management of Chronic Conditions (PRISM-CC).
17 Specifically, the PRISM-CC will be designed to measure patient reported success (or difficulty)
18 self-managing in each of the domains of the TEDSS conceptual framework (see below).[20] The
19 PRISM-CC aims to overcome the limitations of current self-management measures. A
20 conceptual framework that includes domains of relevance to patient experiences forms its
21 foundation, enabling patients and health providers to identify areas of difficulty and design
22 individualized care. PRISM-CC will also facilitate research to isolate and test critical ingredients
23 of self-management programs, and related social and environmental determinants of the different
24 domains. It will be designed and validated for patients with single and multiple chronic
25 conditions.
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36 METHODS AND ANALYSIS

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39 Development of the PRISM-CC will follow the *PROMIS® Instrument Development and*
40 *Validation Scientific Standard, Version 2.0*. [35] This paper first describes the preliminary
41 development of the PRISM-CC (Phases 1 and 2) then outlines the protocol for the final study
42 (Phase 3). Phase 1 was completed in the fall of 2018 by generating a bank of potential items
43 from existing measures and available qualitative data material (Figure 1). During Phase 2,
44 completed in February, 2020, items were tested in an online survey (n=40 persons with multiple
45 chronic conditions), followed by cognitive interviews to select potential items for further testing.
46 In Phase 3, the bank of potential items will be administered to a large and diverse sample of
47 persons with chronic conditions (N~750) between March and November 2020. Item analysis,
48 dimensionality assessment, scaling and preliminary validation of the PRISM-CC will then be
49 conducted. The expected completion date is early 2021.
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5 *PUT FIGURE 1 ABOUT HERE: Flow Diagram for the Development of the Patient*
6 *Reported Inventory of Self-Management for patients with Chronic Conditions (PRISM-*
7 *CC)*
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11 **Patient and Public Involvement**

12 In developing a patient reported outcome measure, inclusion of “patients”, both as participants
13 and research partners is important. Patient perspectives and involvement have, and will continue
14 to be an integral part of development of the PRISM-CC. Two members of the research team are
15 ‘patient-partners’ (community members, each living with multimorbidity and/or complex chronic
16 health conditions), and other members of the research team live with multimorbidity. These team
17 members have and will continue to be involved in project planning and key decision-making
18 meetings. For example, during Phase 1 and 2, patient-partner team members aided in the
19 development and refinement of the items, provided feedback on the design and usability of the
20 first online survey, and facilitated participant recruitment. Their continued input will be sought
21 throughout the development of PRISM-CC, including the calibration study, format of the final
22 PRISM-CC outcome measure and project dissemination. Additionally, patient participants with
23 chronic conditions provided original data to inform PRISM-CC item development through
24 survey and cognitive interviewing processes. Further data collection from patient participants
25 will play an important role during Phase 3.
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41 **Phase 1: Generate potential items for each domain in our conceptual framework**

42 **(completed)**

43 Due to its comprehensiveness, recency, and applicability to patients with multiple conditions, the
44 Taxonomy of Every Day Self-management Strategies (TEDSS), a conceptual framework which
45 describes the everyday strategies people use to live with and manage their conditions was chosen
46 to guide development of the PRISM-CC. It incorporates a broad and inclusive definition of self-
47 management.[8, 15] The construction and validation of the TEDSS conceptual framework is
48 described by Auduly et al, 2019.[20] Briefly, TEDSS was developed using concept mapping
49 methodology,[36] then refined and validated using original data from individuals with one or
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more neurological conditions. First, data from 77 qualitative and quantitative research papers were analyzed in order to clarify the overlapping concepts of coping, adapting and self-managing a neurological condition.[15] Framework domains (n=7) and subdomains (n=26) were then refined and validated using original data from repeated, structured interviews with 117 individuals with neurological conditions over an eleven month period. Individuals with neurological conditions vary widely by age of onset, trajectory and impact; motor, perceptual, cognitive and psychological symptoms exist in variable combinations, providing a strong foundation for understanding self-management in individuals with multiple conditions. Additionally, many of these individuals also had non-neurological conditions such as heart disease, diabetes and hypertension. To confirm applicability beyond neurological conditions the framework was compared to three additional conceptual frameworks, identified in the literature, which included patients with prevalent and diverse types of chronic conditions.[7, 13, 37] Since PRISM-CC will measure respondents' perceived success (or difficulty) in self-managing each TEDSS domain, TEDSS domain definitions were reframed into PRISM-CC measurement definitions, as shown in Table 1.

Table 1: Domains in the Taxonomy of Everyday Self-management Strategies (TEDSS), and Associated Working Definitions used by PRISM-CC

Domain	TEDSS Definition	PRISM-CC Working Definition
Process Strategies	Strategies used to be well informed and to make good decisions. Often used to support use of other, non-process strategies.	Self-perceived success at seeking information, being aware of choices and making good decisions.
Resource Strategies	Proactively seeking, pursuing and/or managing needed formal or informal supports and resources.	Self-perceived success at seeking, pursuing and/or managing needed formal or informal supports and resources.
Activities Strategies	Finding ways to participate in everyday activities (leisure activities, work activities, household chores) despite problems such as fatigue, pain, memory loss or disability.	Self-perceived success in participating in everyday activities (leisure activities, work activities, household chores).
Internal Strategies	Preventing and managing stress,	Self-perceived success at

	negative emotions and internal distress; creating inner calm.	creating inner calm by preventing and managing stress, negative emotions and internal distress.
Social Interaction Strategies	Managing social interactions and relationships to be able to participate without exposure to negative reactions.	Self-perceived success at disclosing health issues, managing social interactions and relationships.
Health Behaviour Strategies	Maintaining a healthy lifestyle in order to enhance health and limit the risk of lifestyle related illness.	Self-perceived success at maintaining a healthy lifestyle.
Disease Controlling Strategies	Preventing, controlling and limiting symptoms, complications and/or disease progression.	Self-perceived success at managing health conditions including managing medications and treatments, monitoring symptoms, and limiting complications.

Note: A more detailed description of TEDSS domains with examples of patient strategies used in each is provided in supplementary Table 1.

Potential items for each domain in the PRISM-CC were first drawn from outcome measures identified in the scoping review of self-management outcome measures.[21] The context (instructions associated with answering the question), the item, and any stem (initial phrase of the item, repeated across items), response options, recall period, and origin of items were tabulated. Additional items were generated using qualitative data previously collected in Canada to develop and validate the TEDSS framework,[38] and by members of the research team. Grounding items in real-life examples is expected to increase face validity.

The research team reviewed 250 potential items using an iterative process that included assessment of face validity, coherence, relevance and patient-centred wording. No fewer than three research team members participated in the assessment of items in each domain. Based on consensus, items were eliminated if 1) they did not conceptually fit a domain 2) were semantically identical/redundant, 3) the content was too narrow or disease-specific to be applicable to patients with multiple chronic conditions, or 4) the item did not assess patient perception of success or difficulty in self-managing. Item stems and response scales were

developed to meet PROMIS standards and recommendations (e.g. preferred response set options, time reference, context).[35] A total of 30-35 items per domain (n=231) were selected for further assessment for relevance and understanding to persons with multiple chronic conditions.

Phase 2: Assess potential items for relevance and understanding to people with multiple chronic conditions; generate preliminary item bank (completed).

Online Survey #1: People (n=40) with two or more chronic conditions were recruited to complete an online survey of potential items (n=231). The purposive sample was recruited via: posters displayed in public areas and health care settings; newsletters and distribution lists; and social media. Participants had to be able to read/speak English and have self-reported diagnosis of two or more chronic conditions. Interested participants first underwent a screening telephone interview to assess inclusion criteria and gather data needed to achieve maximum variation: age (younger or older than age 50); gender identity (man, woman, or other); high school completion (yes or no); and number of diagnoses and time since diagnoses. The first 20 eligible participants were invited to participate. Subsequent recruitment, using the same methods, was purposive, filling gaps to achieve maximum variation in overall participant profiles.

Surveys were administered using an anonymous online survey platform housed on a Canadian University server. To reduce participant burden, the item pool (total n=231) was divided in half, with each participant rating only 50% of the items. Participants were asked to complete each potential item using a 5-point response scale. They also rated each item for difficulty and importance using a 10-point rating scale.

Item analysis was conducted based on item responses and answers to questions assessing difficulty and importance. Given the small sample size, analyses were considered indicative only and used to flag extremely poorly fitting items and those requiring cognitive interviewing. Response distributions provided evidence of potential floor and ceiling affects, while poor item-rest correlations identified items likely to have poor fit to the domain, or that appeared to be interpreted differently than expected. Exploratory factor analysis was used, with caution given the small sample size, to provide insight into item groupings within domains where many item-

rest correlations were weak. Low mean scores on importance and/or high scores on difficulty provided insight into respondents' views on importance and ease of understanding. Items which performed well on all aspects of the item analysis and were consistently evaluated as easy to understand and important to respondents, were carried forward to Phase 3. Items which showed inconsistency in understandability or importance, or which performed moderately well in the item analysis, were carried forward to the cognitive interviews. Those with overall poor performance were removed from the item bank.

Face to Face Cognitive Interviews: A subsample of survey participants (n=10) were invited, based on availability and maximum variation, to participate in individual cognitive interviews. Participants met individually with trained research staff to assess a version of the survey with 30 to 40 items. This resulted in two to five cognitive interviews per item. One team member conducted the interview, while a second team member took field notes. Interviews were audio-recorded and transcribed verbatim.

Each item was first scored by the participant. This was followed by an interview using "think-aloud" methodology which invited participants to describe how they interpreted it and selected their response.[39, 40] Participants were also asked how alternative instructions or response scales might change their interpretation and/or answer. Finally, participants were asked about the importance and difficulty of items using questions such as *You circled "x" as your response to the question asking about the importance of this item. Please tell me what things you were thinking about when answering this question.*

Text was tabulated by item and analysed to provide insight into interpretation and acceptability of item stems, response scales, and patient oriented language. Specific words or terms found to be unclear, easily misunderstood, or judgemental were flagged for application across all items.

Generation of Preliminary Item Bank: Using findings from the online survey and cognitive interviewing data, each item was assessed for domain coherence, clarity, and understandability. Whether the item measured perceived success or difficulty in self-management and its potential scalability were also considered. To ensure consistent assessment, the first 20 items were

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3 reviewed by the full research team and all other items were assessed by a minimum of two team
4 members. All potential items were assessed for semantic similarity with only the most promising
5 one or two items per group retained. Finally, overall face and content validity of each domain
6 was assessed by ensuring coherence between items and domain definitions. These items (N=105)
7 form the preliminary PRISM-CC item bank for testing in Phase 3.
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10 11 12 13 **Phase 3: Protocol to select and calibrate the final PRISM-CC items in a sample of people** 14 **with chronic conditions and to conduct preliminary validation (to be completed).** 15

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18 **Participants:** Participants will be recruited using the following inclusion criteria: age 18 years of
19 age or older, able to read/speak English, and self-reported diagnoses of one or more chronic
20 conditions. Multiple strategies will be used to recruit participants:
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- 23 1. Posters displayed in public areas, including health care settings,
- 24 2. Posters and information distributed to patients attending group/individual sessions,
- 25 3. Invitations to participate placed in newsletters and/or via relevant distribution lists, and
- 26 4. Social media and free online advertising sites.
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30 All recruitment materials will include the URL to the survey; participants will not be required to
31 contact the research team nor to enter information such as name, address, or health card numbers.
32 Simulations on PROMIS data, based on similar item development methods, show that as few as
33 250 subjects are sufficient for this analyses.[41] However, sample size calculations for
34 confirmatory factor analysis were also performed to inform the needed sample size.[42, 43]
35 Assuming 80% power to differentiate good versus moderate fit (RMSEA of .04 versus .06) in the
36 most complex model: a fully stratified (2-5 groups) non-orthogonal model including mean
37 structures (substantially similar to IRT), with seven domains and a minimum of 4-7 items per
38 domain, a sample size of 587 was determined. We will recruit 750 participants to compensate for
39 loss of power due to non-normality and unequal numbers between groups.
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49 **Online Survey:** When potential participants access the public URL to the online survey, the
50 landing page will include the purpose, inclusion criteria, what participants will be asked to do
51 and information regarding confidentiality and anonymity, compensation and who to contact in
52 case of questions or concerns. Participants will consent by answering 'yes' to the question "Do
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3 you wish to participate in this survey?" The first questions of the survey will be used to confirm
4 eligibility, and those not eligible will receive a thank you message with no further questions
5 asked. The remainder of the survey will consist of 105 potential PRISM-CC items (15-17 items
6 per domain), 10 socio-demographic questions (age, gender identity, country of residence, current
7 living situation, first language, education, types of chronic conditions, status of general health,
8 status of general mental health, and impact of chronic condition(s) on life), and a six-item
9 validated self-management tool, the Self-Efficacy for Managing Chronic Disease Scale
10 (SEMCD).[44] Based on the Phase 2 survey, 10-20 seconds per item is a reasonable expectation
11 resulting in a total time of 20-30 minutes to complete the survey. Participants will have the
12 option to leave the survey at any time, returning to complete it later.
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22 At the end of the survey, participants will have the opportunity to enter their name and email
23 address for a chance to win one of four \$100.00 gift cards. This will be collected in a second,
24 unconnected survey and will be used only to select winners of the gift cards.
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29 ***Dimensionality and Calibration Analysis:*** Stages of analysis will include item analysis,
30 assessment of dimensionality, and calibration.[35, 45] Analysis will be done in Stata and R
31 (packages ltm and MultiLCIRT). Item analysis will be used to identify and exclude items that are
32 highly skewed, lack variance, or are weakly correlated with other items in their domain.
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38 The structural validity of the items against our conceptual model will be empirically tested.
39 Given the strong conceptual model and qualitative validation, confirmatory factor analysis
40 (CFA) will be the primary analytic method to evaluate whether the data fits our seven-domain
41 conceptual framework based on TEDSS.[46, 47] Fit will be assessed using multiple indices (e.g.
42 Comparative Fit Index, Tucker Lewis Index, RMSEA and SRMR).[47] A joint model will
43 estimate the correlation between domains. CFA will also be used to help determine if any
44 domain should be collapsed (augmented by results from the qualitative dimensionality
45 assessment described above), and to assess measurement invariance by gender identification, age
46 group, education and health status groups. Modification indices will identify items with high
47 cross loadings across domains. If the CFA for any of the domains show poor fit, exploratory
48 factor analysis will be conducted to explore structural patterns of the items.
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5 Items within each domain will be calibrated with item response theory (IRT).[35] Well calibrated
6 IRT items can be incorporated into computerized adaptive testing to measure constructs using as
7 few as 4-5 items, thus reducing response burden.[48] Assumptions for IRT scaling (local
8 independence and monotonicity of items) will be assessed. Items violating assumptions will be
9 excluded, or further examined in the IRT analysis to determine their influence on parameter
10 estimates. Samejima's Graded Response Model (GRM) will be the preferred modeling approach,
11 but other polytomous IRT models will also be estimated for comparison. [35, 45, 49] The
12 performance of each item/response category will be reviewed using category response curves
13 and estimates of item information. Differential item functioning (DIF) analysis will be conducted
14 by age, gender, self-reported health status, number of chronic conditions, and education. For
15 each domain, we will seek a set of best items that provide reliable estimates across levels of the
16 latent construct, and which do not have differential item functioning.[45, 49]
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27 **Sample Size**

28 Simulations on PROMIS data, based on similar item development methods, show that as few as
29 250 subjects are sufficient for this analyses.[41] However, sample size calculations for
30 confirmatory factor analysis were also performed to inform the needed sample size.[42, 43]
31 Assuming 80% power to differentiate good versus moderate fit (RMSEA of .04 versus .06) in the
32 most complex model, a fully stratified (2-5 groups) non-orthogonal model including mean
33 structures (substantially similar to IRT), with seven domains and a minimum of 4-7 items per
34 domain, a sample size of 587 was determined. We will recruit at least 750 participants to
35 compensate for loss of power due to non-normality and unequal numbers between groups.
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45 ***Preliminary Validation Analysis:*** Preliminary validity will be assessed by examining known
46 relationships between each TEDSS domain and the generic Self-Efficacy for Managing Chronic
47 Disease Scale (SEMCD), a well-known and highly used outcome measure of confidence to
48 manage a chronic condition.[44] The SEMCD is used in research, clinical, and practice settings
49 to measure self-management. Evidence suggests this tool is a reliable generic measure of self-
50 management with evidence of construct validity.[25]
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In addition to the SEMCD, individual TEDSS domains will be validated by examining associations with the known correlates of education, general and mental health (including number of chronic conditions) and/or a measure of impact on everyday life (see Table 2). Level of education (categorical) and number of chronic conditions will be extracted from collected demographic information. Self-reported general and mental health will be assessed using common single item measures from the Canadian Community Health Survey: “In general, would you say your health/mental health is excellent, very good, good, fair or poor?”.[50] The impact of the chronic condition will be measured using a single Likert response item: “Overall, how much do you feel that your chronic condition(s) affect(s) your life (not at all – extremely).[38]

Table 2: Known Relationships by TEDSS Domain.

TEDSS Domain	Known Relationship
Process	Positive relationship with education.[51, 52]
Resources	Positive relationship with education.[53–55]
Disease Management	Inverse relationship with number of conditions.[56, 57]
Health Behaviours	Inverse relationship with general health.[58] Positive relationship with education.[59, 60]
Activities	Inverse relationship with participation in everyday life.[53]
Internal Social Interaction	Positive relationship with mental health.[53, 60] Positive relationship with mental health[53]

Bivariate analysis and multivariate analyses will be conducted to examine relationships between the TEDSS domains and relevant categorical variables (education, general health, mental health, and impact on participation).

ETHICS AND DISSEMINATION

All procedures will adhere to the Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. Phase 1 did not include collection of original data; therefore, ethics approval was not required. Ethics approval for Phase 2 and 3 has been obtained from the Nova Scotia Health Authority Research Ethics Board.

This study has and will continue to use an integrated knowledge translation approach.[61] Team members include patient-partners, policy makers and managers in primary care. All have and will shape the research process. A summary of our results will be posted on our website, accessible to the public. The Primary Health and Chronic Disease Portfolio in the Nova Scotia is actively using the conceptual framework employed for the PRISM-CC to guide assessment and planning in primary care and chronic disease management, and has provided extensive consultations to our team on the attributes of PRISM-CC that will be required to facilitate its integration into care. To facilitate uptake and use, the final PRISM-CC will be made available for research and clinical care at minimal or no cost.

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AUTHOR CONTRIBUTIONS

Conceptualisation: TP, GK, AA, and GW. Methodology: TP, GK, AA, GW, KP, and ACK. Project Administration: TP, GK, KP, and TS. Data Curation: TP, GK, AA, KP, and ACK. Funding acquisition: TP, GK, AA, TS, GW, and ACK. Methodology: TP, GK, AA, KP, GW, and ACK. Writing, reviewing and editing: all authors.

COMPETING INTERESTS

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Legend (Title) for Figure 1: Flow Diagram for the Development of the Patient

Reported Inventory of Self-Management for patients with Chronic Conditions (PRISM-CC)

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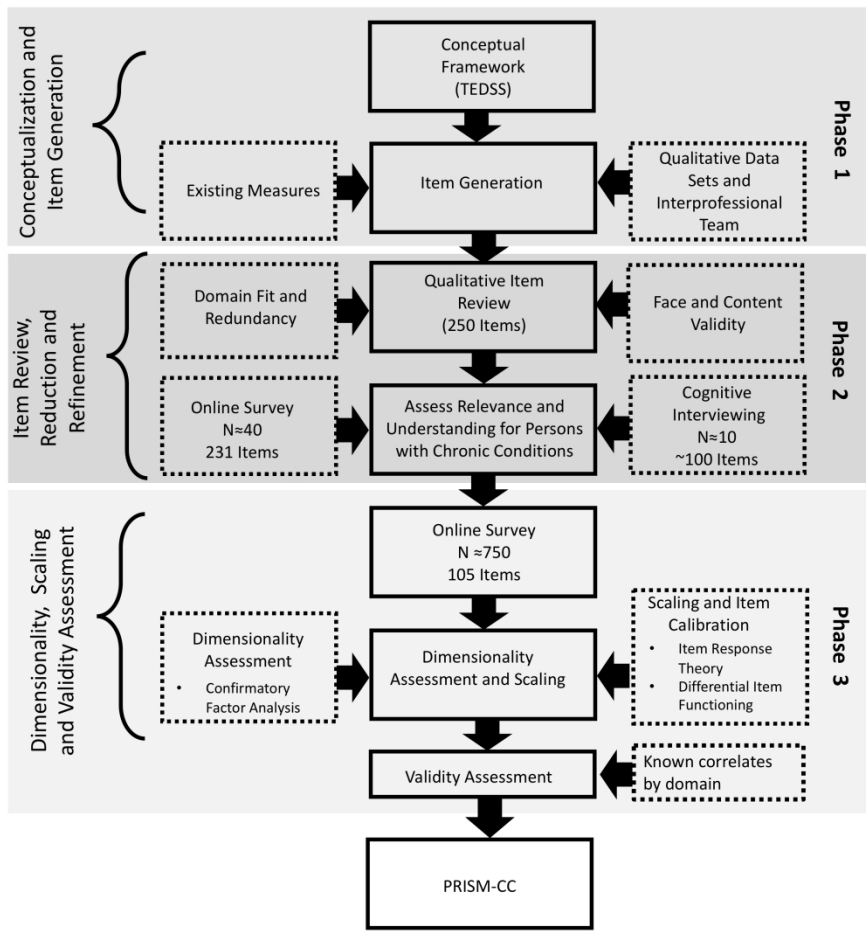


Figure 1: Flow Diagram for the Development of the Patient Reported Outcome Measure for Patients with Chronic Conditions (PRISM-CC)

269x270mm (300 x 300 DPI)

Table S1. Taxonomy of Everyday Self-Management Strategies (TEDSS) with Description of Types of Strategies Used in Each Domain

TEDSS Domain	Types of Self-Management Strategies
<p>Process Strategies Strategies used to be well informed and to make good decisions. Often used to support use of other, non-process strategies.</p>	<ul style="list-style-type: none"> • Awareness and problem solving: Proactive strategies to become aware of choices and consequences of disease related problems in everyday life, trying to find alternative solutions and making informed decisions. • Information-seeking: Researching and seeking information regarding, for example, one's disease, symptoms and treatment, living with illness, the health, social service and insurance systems.
<p>Resource Strategies Proactively seeking, pursuing and/or managing needed formal or informal supports and resources.</p>	<ul style="list-style-type: none"> • Self-advocating: Actively pursuing access to health-care providers, social systems, and legal rights. Speaking out against discrimination. • Seeking and managing everyday support: Judging the need for support, asking for support, planning support, and keeping a sense of autonomy despite receiving support. • Seeking and managing health/social care needs and paid support: Navigating and managing the formal support health-care systems (health, social, financial) in order to receive treatment, referral, equipment, etc. Includes seeking health care, attending appointments and preparing oneself for consultations.
<p>Activities Strategies Finding ways to participate in everyday activities (leisure activities, work activities, household chores) despite problems such as fatigue, pain, memory loss or disability.</p>	<ul style="list-style-type: none"> • Pace, plan and prioritize: Using time wisely, planning the day, resting to conserve energy, adapting activities to current functional level and making important activities a priority. • Organizing routines and systems: Using tables, charts, lists, reminders, tracking systems and routines to organize information, items and equipment and to carry out activities. • Aids and physical adaptations: Using aids (e.g., canes, mug with straw), adapting environments (e.g., rearranging furniture to ease movement, ramps) and adapting behaviors (e.g., having a hand on the wall while moving around) to facilitate activities. • Engage in valued activities: Making time to do the activities that are important and bring meaning and value to the individual. For example, being with family, taking a walk, painting, attending a concert.
<p>Internal Strategies Preventing and managing stress,</p>	<ul style="list-style-type: none"> • Acceptance: Accepting issues and conditions judged to be out of one's control and gaining inner peace with unchangeable circumstances.

TEDSS Domain	Types of Self-Management Strategies
negative emotions and internal distress; creating inner calm.	<ul style="list-style-type: none"> • Staying Positive: Deliberately adopting a positive attitude to limit negative feelings and generate positivity. Re-evaluating one's situation, finding meaning and perspective in life, sometimes to fight depression. • Controlling Stress and Negative Emotions: Controlling emotions in order to remain calm, reduce anxiety and/or prevent being overwhelmed by emotions. Using techniques like meditation, breathing techniques and relaxation, or deliberately avoiding thinking about problems, symptoms or future risks by focusing on other activities or thoughts. • Allowing Time for Sadness and Grief: Expressing feelings (e.g., crying or venting) with the intention to feel better afterwards. • Seeking Comfort in Faith and Spirituality: Praying, talking with religious leaders or reading spiritual texts, in order to feel inner comfort.
Social Interaction Strategies Managing social interactions and relationships to be able to participate without exposure to negative reactions.	<ul style="list-style-type: none"> • Disclose condition: Deciding to whom to disclose information about condition, including what and how much information is given to each person. • Choosing social relationships and situations: Prioritizing and investing in selected interpersonal relationships. Avoiding emotionally demanding or discriminating interactions; ensuring a sense of control. • Stay in contact: Staying in contact with family or friends using traditional and new methods of connecting, sometimes to overcome cognitive or mobility problems (e.g., using social media when home bound). • Optimize social interactions: Facilitating interactions (talking slowly, rephrasing sentences, explaining needs). Controlling misunderstood symptoms (e.g., spasms or drooling), or emotions (e.g., anger or anxiety). • Use humor: Using humor or laughter to de-dramatize a situation.
Health Behavior Strategies Maintaining a healthy lifestyle in order to enhance health and limit the risk of lifestyle related illness.	<ul style="list-style-type: none"> • Physical exercise: Being physical active (e.g., sports, gym exercise, walking, therapeutic stretching, or swimming) within level of functional ability. • Mental exercise: Keeping mentally fit (e.g., brain teasers, games, puzzles, committee membership or volunteering). • Diet: Maintaining healthy eating habits. Eating more healthy foods (e.g., vegetables, fruit, protein, water consumption, vitamins) and avoiding unhealthy foods (e.g., sweets, deserts, processed foods).

TEDSS Domain	Types of Self-Management Strategies
	<ul style="list-style-type: none"> • Sleep hygiene: Creating a healthy sleep routine, including regular bedtime, calm activities before sleeping, attention to mattress and pillow, and use of needed, routine daily naps.
Disease Controlling Strategies Preventing, controlling and limiting symptoms, complications and/or disease progression.	<ul style="list-style-type: none"> • Manage medication and treatments: Taking prescribed medication and/or over the counter medication. Completing treatments at home. • Prevent symptoms and complications: Accommodating and controlling symptoms and disease related complications (limiting the risk of falling, having an annual flu shot, avoiding seizure triggers) and controlling/limiting existing symptoms (stretching, wound care, hot packs to limit pain). • Use complementary medicine: Using supplements (e.g., herbal remedies, probiotics etc.) and complementary strategies (massage, conductive education).

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