


# BMJ Open Effectiveness of an eHealth self-management tool for older adults with multimorbidity (KeepWell): protocol for a hybrid effectiveness–implementation randomised controlled trial

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## ABSTRACT

**Introduction** In response to the burden of chronic disease among older adults, different chronic disease self-management tools have been created to optimise disease management. However, these seldom consider all aspects of disease management are not usually developed specifically for seniors or created for sustained use and are primarily focused on a single disease. We created an eHealth self-management application called ‘KeepWell’ that supports seniors with complex care needs in their homes. It incorporates the care for two or more chronic conditions from among the most prevalent high-burden chronic diseases.

**Methods and analysis** We will evaluate the effectiveness, cost and uptake of KeepWell in a 6-month, pragmatic, hybrid effectiveness–implementation randomised controlled trial. Older adults age ≥65 years with one or more chronic conditions who are English speaking are able to consent and have access to a computer or tablet device, internet and an email address will be eligible. All consenting participants will be randomly assigned to KeepWell or control. The allocation sequence will be determined using a random number generator. Primary outcome is perceived self-efficacy at 6 months. Secondary outcomes include quality of life, health background/status, lifestyle (nutrition, physical activity, caffeine, alcohol, smoking and bladder health), social engagement and connections, eHealth literacy; all collected via a Health Risk Questionnaire embedded within KeepWell (intervention) or a survey platform (control). Implementation outcomes will include reach, effectiveness, adoption, fidelity, implementation cost and sustainability.

**Ethics and dissemination** Ethics approval has been received from the North York General Hospital Research and Ethics Board. The study is funded by the Canadian Institutes of Health Research and the Ontario Ministry of Health. We will work with our team to develop a dissemination strategy which will include publications,

## Strengths and limitations of this study

- We are using a hybrid implementation–effectiveness randomised control design to evaluate the KeepWell application, which will help identify important intervention–implementation interactions needed to optimise its applicability and uptake by older adults.
- The KeepWell application is innovative as it provides evidence-based, customised lifestyle advice for any combination of the 10 most common high-burden chronic conditions affecting older adults.
- A team of patient partners and other stakeholders including clinicians and researchers codesigned the KeepWell tool, which will increase its relevance and use by older adults.
- Limitations of our study are the inclusion of only English-speaking older adults with technology and internet access, which may limit the generalisability of our findings.

presentations, plain language summaries and an end-of-grant meeting.

**Trial registration number** NCT04437238.

## INTRODUCTION

The burden of chronic disease (long-term health condition that requires ongoing management for many years or even decades) is a global phenomenon, particularly among seniors<sup>1</sup> who are the largest growing proportion of the population. In Canada, seniors (age ≥65 years) in 2019 represented 17.5% of the total population<sup>2</sup> with projections that one in four Canadians will be older adults by 2031.<sup>3</sup> Ageing is an expensive process, as

10% of seniors who have the most complex health needs account for 60% of the total annual healthcare spending in many Canadian provinces.<sup>4</sup> As the disease burden grows in the global population, the associated healthcare costs will become unsustainable. Therefore, we need to adapt our current models of care to accommodate this shifting demand. Additionally, the impact of difficult situations such as the COVID-19 pandemic on healthcare delivery can compound the problem, highlighting the need to find alternative solutions to in-person care. In response, different chronic disease management strategies have been created with a central aim to facilitate ongoing, proactive and preventive support for optimal chronic disease management. Many of these are based on Wagner's chronic care model, (CCM)<sup>5</sup> which suggests that four elements need to be addressed to improve outcomes, including: self-management support across the community; as well as health system considerations focused on the delivery system, decision support and clinical information systems.<sup>5</sup> A systematic review of chronic disease management tools identified patient education and self-management are needed for optimised disease control.<sup>6</sup> Self-management has been defined as: 'the intrinsically controlled ability of an active, responsible, informed and autonomous individual to live with the medical, role and emotional consequences of his chronic condition(s) in partnership with his social network and the healthcare provider(s)'.<sup>7</sup> In the context of multimorbidity, optimised healthcare delivery also requires a patient-centred approach whereby patient preferences are considered alongside clinician-driven treatment decisions. In fact, clinical practice guidelines on multimorbidity emphasise the importance of this approach.<sup>8</sup> A recent review found that top health-related patient preferences of older patients with multimorbidity are health outcome prioritisation and goal setting and self-management.<sup>9</sup> In recent years, self-management tools have been acknowledged as an effective way to optimise disease management because persons can 'function on their own behalf in health promotion, disease prevention and management'.<sup>10 11</sup> Self-management tools also have the potential to alleviate time and resource burdens on primary care healthcare professionals (eg, physicians, nurses, dietitians and pharmacists) who most often are left to address all aspects of disease management (ie, risk assessment, diagnosis and treatment). In particular, online self-management tools have potential because they can improve health outcomes effectively at a low cost,<sup>6 12-16</sup> are easily scalable and can reach a broader population of older people with chronic diseases.<sup>6</sup> In fact, online tools are particularly relevant for supporting older adults with complex care needs in their homes, particularly during difficult circumstances requiring isolation and distancing such as the COVID-19 pandemic.<sup>17</sup> In the last decade, the use of technology among older populations has grown significantly and is expected to continue expanding.<sup>18-20</sup> Surveys of older adults indicate that they are interested in using the internet to access health information, are using

the Internet or email and are accessing social networking sites such as Facebook, YouTube and Twitter.<sup>18-22</sup>

While self-management tools have shown some success in promoting health, many have shown varying degrees of effectiveness.<sup>6 12</sup> Reasons may be that these tools do not consider all aspects of disease management or all elements of the CCM. Additionally, they are not usually developed specifically for seniors or created for sustained use and are primarily focused on a single disease.<sup>6</sup> Such a narrow focus, in particular, fails to address the growing number of seniors with multiple chronic conditions, which accounts for more than half of seniors aged 65 years and older who are managing at least two or more chronic conditions such as, diabetes, dementia, heart failure and depression.<sup>12 13</sup> As our population ages, an increase in multiple chronic conditions translates to increased risk of functional limitations and possible admission to acute or long-term care facilities.<sup>6 12</sup> The projected health outcomes of seniors, therefore, continue to remain poor, and the quality and efficiency of care suboptimal, with only about 55% of patients receiving the recommended care.<sup>5</sup> To respond to these challenges, we created an eHealth self-management application called 'KeepWell' that supports seniors with complex care needs in their homes. KeepWell is a patient-centred (ie, driven by patients), self-management tool that incorporates the care for two or more chronic conditions from among the top 10 high-burden chronic diseases (ie, highly prevalent and associated with significant morbidity and mortality) of older adults in Canada. KeepWell was built on a strong evidentiary base including a systematic review alongside a realist review,<sup>23 24</sup> which, respectively, investigated the effectiveness of tools addressing multiple chronic conditions,<sup>23</sup> and their underlying mechanisms and context.<sup>24</sup> Findings of these reviews and a codesign process involving input from our team of researchers and clinicians, a patient working group of 10 older adults and our technology partner (Quality of Care (QoC) Health) informed the design of the KeepWell responsive web application. Once the functional prototype of KeepWell was created, we conducted a usability and pilot evaluation with 20 older adults to optimise its use by older adults.<sup>25</sup>

The objective of our study is to evaluate the effectiveness, cost and uptake of KeepWell in a pragmatic, hybrid effectiveness-implementation randomised controlled trial (RCT).

## METHODS AND ANALYSIS

### Study design

We will evaluate the effectiveness and uptake of the KeepWell application in a 6-month, pragmatic, hybrid effectiveness-implementation RCT<sup>26</sup> for optimising and sustaining the self-management of older adults with multiple chronic diseases in the community. We will use the type 2 design, which facilitates the simultaneous investigation of the effectiveness of an intervention while rigorously testing the implementation strategy.<sup>26</sup> The implementation evaluation process will be guided by the

Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM)<sup>27</sup> and Proctor *et al's*<sup>28</sup> frameworks. The results will be reported using the The Consolidated Standards of Reporting Trials (CONSORT)-EHEALTH Checklist<sup>29</sup> and the Template for Intervention Description and Replication Checklist.<sup>30</sup>

### Theoretical basis of our work

We used the Knowledge-to-Action (KTA) model to guide our methods.<sup>31</sup> Our team has experience applying the KTA framework in creating technology-based interventions.<sup>32 33</sup> We have also adapted an integrated knowledge translation (IKT) strategy whereby our stakeholder team members (many of whom are also authors on this paper) helped create the KeepWell tool across the various stages of its development.<sup>23–25</sup> For example, the full IKT team met three to four times per year (in-person or via teleconference) with more frequent interactions with stakeholders at strategic timepoints in the development of KeepWell. For example, we engaged clinicians more frequently during the development of the evidence-based lifestyle recommendations, health services and KT researchers to help inform study design, and patient partners, who were engaged more frequently during the active development and pilot testing stages of the process.

### Patient population and eligibility criteria

Older adults will be identified with support from: (i) the retired teachers of Ontario (RTO); (ii) the University of Toronto Primary Care Research Network (UTOPIAN) and (iii) our partnering clinicians (geriatricians and family physicians) and their affiliated sites: North York General Hospital (NYGH), St. Michael's Hospital of Unity Health Toronto, Sunnybrook Health Sciences Centre and St. Peter's Hospital. All these recruitment sources have a roster of older adults with multiple chronic conditions via their membership (eg, RTO) or affiliated primary care and geriatric clinics (UTOPIAN and partnering clinicians). Study eligibility criteria are: (i) age  $\geq 65$  years; (ii) have one or more of the following chronic conditions: diabetes, heart failure, cardiovascular disease, dementia, chronic kidney disease, osteoporosis, osteoarthritis, rheumatoid arthritis, Chronic Obstructive Pulmonary Disease (COPD), depression, urinary incontinence, stroke; (iii) English speaking; (iv) have access to a computer or tablet device; (v) high-speed internet access; (vi) have an email address and (vii) able to consent. Consent-giving capacity will be assessed using the validated, 10-item, University of California Brief Assessment of Capacity to Consent Tool.<sup>34</sup>

### Recruitment

We have created a recruitment poster, which includes a phone number and email address dedicated to this research project as well as a website with information about eligibility criteria and the consent process (online supplemental appendix A). This poster will be distributed according to the following strategies: (i) via an email list-serv from RTO with a membership of more than 80 000

older adults across Canada; (ii) directly to older adults by our family physician and geriatrician partners during an in-person, phone or virtual patient visit (eg, using a web-conferencing application) or through their clinic staff and (iii) via advertisements on social media sites (eg, Facebook and Twitter) or online classified advertising services (eg, Kijiji and Craigslist). Potential participants will self-refer after reviewing the poster or a full-length study information page from the NYGH website by contacting the research coordinator via email or phone. This will trigger an enrolment phone call with the potential participant and the study coordinator involving the assessment of their study eligibility, consenting ability, as well as verbal consent (online supplemental appendix B). Non-consenting respondents will be asked to provide a reason for their decision. Recruitment will be performed on a rolling basis starting in December 2020.

### Randomisation and blinding

All consenting participants will be randomly assigned to a unique identification number and KeepWell password linked to a particular randomisation sequence (intervention or control) during the enrolment phone call using a 1:1 ratio. The allocation sequence will be determined using a random number generator by the study coordinator; participants will be the unit of randomisation. At the conclusion of the enrolment phone call by two study coordinators, consenting participants will receive an email with a link to KeepWell (intervention condition) or to a link to an online survey (via SurveyMonkey) to complete a health risk assessment questionnaire (control condition). The research coordinator will have the master list of the allocation sequence and logins. Allocation will, therefore, be concealed because this list will not be shared with the research team. To protect against sources of bias, investigators, outcome assessors and data analysts will be blinded to the randomisation sequence. Blinding of older adults will not be possible given that the intervention is a standalone, web-based application and the control condition is usual care (no access to KeepWell).

### Intervention and control groups

**Intervention:** Participants allocated to the intervention group will be given access to KeepWell, which is a fully functional, standalone, user-responsive, eHealth application aimed at supporting the self-management of older adults with multimorbidity ([www.keepwell.care](http://www.keepwell.care)). **Table 1** highlights the details of the KeepWell application features and function. KeepWell can be used on computers and tablet devices (eg, iPad and Android tablet) and has innovative features that most other chronic disease solutions do not have (see **table 1**): (i) a multidisease focus (it can generate lifestyle advice for any combination of the top 11 most common chronic conditions affecting older adults (eg, diabetes, heart disease, osteoporosis, depression and dementia); (ii) an animated, talking avatar health coach that walks users through a health prioritisation and goal setting exercise. This is important as most self-management

**Table 1** Features and function of the KeepWell application

Feature	Description and function
Standalone and accessible	KeepWell is not integrated so it can be accessed and used by older adults regardless of where they live and used at any time on computer or table devices.
Multidisease focus	KeepWell can generate, evidence-based lifestyle advice for any combination of the top 11 high-burden chronic conditions (ie, highly prevalent and associated with significant morbidity and mortality) commonly affecting older adults.
Wellness vision	A feature of KeepWell to help participants to think about a personal reason for why they want to keep well, which may help to motivate them in their everyday life and activities. It involves asking participants to fill in the following statement: 'I want to keep well so that I can:...' and to select images from a series of wellness categories that are related to wellness (physical health, emotional wellness, creative and intellectual pursuits, hobbies and volunteering, friends and family, and spiritual wellness).
Avatar health coach	An animated avatar health coach with optional voiceover that guides users through the KeepWell application, particularly through the initial sections that require completing tasks (ie, wellness vision, HRQ and a health prioritisation and goal setting exercise).
Health Risk Questionnaire (HRQ)	The HRQ covers three risk dimensions: health (demographics, chronic diseases and risks), lifestyle (physical activity, diet, smoking, alcohol, caffeine, bladder health), and social and emotional well-being (social isolation, loneliness). It also includes validated questionnaires to assess self-efficacy, <sup>47 48</sup> quality of life, <sup>50</sup> physical activity, <sup>51</sup> nutritional health, <sup>52</sup> social connectedness <sup>53</sup> and eHealth literacy. <sup>54</sup>
HRQ results output 1	Summary of the HRQ results: after completing the HRQ, the KeepWell user will receive a table outlining their responses to all questions across the three health dimensions (health background; lifestyle; social and emotional well-being) of the HRQ.
HRQ results output 2	What HRQ results mean and why they are important: the second output that KeepWell users receive is a table with more detailed information about the user's HRQ results. For each health condition or risk factor, there is an explanation of what it means, and why it is important for the tool user to know about it.
Action planning: selection of health priorities	After viewing their HRQ results, the next part of the journey for KeepWell users is to create an action plan that is customised just for them. Based on their responses to the HRQ, the health coach avatar walks KeepWell users through an exercise to select their health priorities. Depending on the results of the HRQ, the person may see the picture of one, two, three or all six of the lifestyle areas that KeepWell addresses (alcohol intake, caffeine intake, diet, physical activity, smoking and bladder health). KeepWell users are prompted to select a maximum of two lifestyle areas to work on at any given time, and to think about those that they consider important and feel ready to tackle right now. It can be overwhelming for anyone to attempt to work on all lifestyle areas at once. The complexity of multiple lifestyle advice can hinder self-management in older adults with multimorbidity. The avatar health coach advises that it's a good idea to start small by selecting only one or two areas, which will make it easier for them to manage and therefore a better chance for success in the long term. Furthermore, tool users can always come back later to select other lifestyle areas to work on once they have a handle on the first two that they selected.
Action planning: setting goals for each health priority	Once KeepWell users select their lifestyle priority areas, the avatar health coach walks them through a goal setting exercise for each. For example, if the first lifestyle area selected is diet, the user will receive customised diet recommendations organised according to different food types such as vegetables, fruit, whole grains. For each food type, there is a description of the serving size for that food, and the recommended number of servings per day for that food. Next, the tool user can set their food goals for up to three food types using dropdown menus, and for each food type, they can select the number of servings for that food. This exercise works in a similar way for the other five lifestyle areas.
Action plan	Once KeepWell users complete their goal setting exercise, they will receive an evidence-based Action plan with lifestyle advice customised to their identified health risks (generated from the HRQ) as well as the health priorities and goals they had set. The Action plan includes everything they have worked on within KeepWell up to that point: their wellness vision, customised plan for the two lifestyle areas (which shows their recommendations as well as the goals they set for each), tips as well as resources for achieving their goals (eg, if they selected the lifestyle area for diet, they will receive a shopping list). Finally, users are given suggestions about how to put their plan into action. These include: (i) printing their action plan for themselves, family member or their healthcare professional; and (ii) to track their activities using the KeepWell tracking tool.

Continued

Table 1 Continued

Feature	Description and function
Interactive lifestyle tracking tool	KeepWell has an interactive lifestyle tracker, which allows participants to track up to six lifestyle areas (diet, physical activity, alcohol, caffeine, smoking and bladder health) that have been identified as their health priority area and for which they can set a goal for. Tracking is a great way to stay motivated, and it has been proven to help people achieve goals. Once a participant sets a goal for a lifestyle area, they can track their activities daily or weekly. Tracking is set up similarly for each types of lifestyle area. For example, for caffeine, alcohol and smoking, tracking involves selecting the amount that was consumed using dropdown menus. For bladder health, it's to track the number of Kegel exercises they had performed. For physical activity, users can select from among a wide range of pictures to select the type of activity (including whether this was a light, moderate or vigorous activity) and then the number of minutes they spent doing each activity using dropdown menus. For diet, people can track what they ate that day by clicking on the number of servings for each of the foods they set a goal for using a dropdown menu. To make it more fun, each food type that is tracked flies onto a plate so that users can see everything they ate that particular day. There is also a tracker for weight, but this is an optional feature in KeepWell. The idea is that tracking weight may help users see how their body is changing as a result of their new lifestyle habits.
Tracking progress viewing tool	The tracking progress viewing tool can be used by KeepWell users to view their tracking history for each of their priority lifestyle areas and to see their progress over time. When users open up the progress viewing tool, they will see their tracking history for a particular week. Users can toggle between each of their two lifestyle areas to see their tracking history. For example, if diet was one of the lifestyle areas they tracked, the user will see a green circle for tracked days and an open-circle for days that they did not track. The idea is that users get rewarded for tracking rather than goal attainment which helps maintain motivation and minimise disappointment. The progress viewing tool is set up similarly for the other five lifestyle areas.
Gamification rewards	Once participants have tracked their lifestyle activities for at least two consecutive days, they receive congratulatory messages and trophies. The more participants track, the higher the rewards and trophies they receive.
My journal	KeepWell allows participants to create their own, private journal to record anything they like (eg, thoughts, reflections about their wellness journey, to help organise and record their activities and events or anything they like). There is also an option for users to select a category for their journal entry, to view the history of all their previous entries, and to search by topic, category or by the text within their entries. The journal feature can be accessed from the home page or from any page within KeepWell.
Menu	The menu star is a great resource for KeepWell users to access different features and functions of KeepWell. It is accessible on any KeepWell page, and allows users to view and modify their wellness vision, to turn the audio on or off, to change to their preferred measurement units (metric or imperial), to update their email, to access instructional videos, to provide feedback about their KeepWell experience, ask for help, and to log out.
Resources	Extensive resources library, which has links to additional high-quality health and lifestyle information across topics that may be of interest to older adults (ie, social, mental and emotional health, sexual health, physical health, and disease-specific information). There is also a section that includes inspiring videos of other older adults who are keeping well.
Instructional videos	The menu includes five instructional videos designed to provide information and instructions for completing tasks and using the various features of KeepWell. The videos are available through the Menu star and include an: introductory video (an overview of all the features and functions of KeepWell), how to use the menu, how to use the journal, how to create an action plan, and how to track lifestyle activities and to view progress.
Home page	The KeepWell home page provides access to the many tools and resources to help KeepWell users put their plan into action. It has six tabs corresponding with all the activities they can perform at any time: (i) to track their lifestyle activities in the areas they have selected as priority; (ii) to view their tracking progress; (iii) to create journal entries or view their journal history; (iv) to view or update their lifestyle priorities and/or goals through their existing action plan; (v) to view their HRQ results and (vi) access the resources page, which provides other helpful health information that may be of interest to older adults including inspiring videos of other older adults keeping well.

tools are designed to fit patients' condition rather than their health priorities, which does not address their specific needs.<sup>35–37</sup> Establishing patient goals, values and

priorities not only ensures that their views and needs are considered to enhance the self-management process but they also simplify the burden of multimorbidity care<sup>38</sup>;

(iii) a Health Risk Questionnaire (HRQ) covering three risk dimensions: health (chronic diseases), lifestyle (physical activity, diet, smoking, alcohol, caffeine and bladder health) and social and emotional well-being (social isolation and loneliness); (iv) an evidence-based Action plan with lifestyle advice customised to the user's identified health risks as well as their personal health goals and priorities and (v) other eHealth self-management tactics that have been shown to improve health outcomes (ie, interactive lifestyle trackers<sup>39 40</sup> and a journaling feature).<sup>41</sup> KeepWell also has an extensive resources library, which has links to additional high-quality health and lifestyle information across topics of interest to older adults (ie, social, mental and emotional health, sexual health, physical health and disease-specific information). **Control:** Participants allocated to the control condition will receive care as usual but will be asked to complete the HRQ at baseline, 3-month and 6-month follow-up via an online survey to collect outcomes data. The control group will receive full access to KeepWell at the conclusion of the study. To maximise adherence to protocols, both groups will receive automated reminder emails.

### Development of the KeepWell application

The KeepWell application was informed by: (i) knowledge syntheses: a systematic review to investigate the effectiveness of complex multimorbidity interventions for older adults<sup>23</sup>; and a realist review to unpack their underlying mechanisms<sup>24</sup>; (ii) evidence-based clinical practice guidelines across 11 high-burden chronic conditions (eg, diabetes, heart disease, dementia and COPD) and (iii) an iterative codesign process.<sup>25</sup> The codesign process involved engaging a working group of 10 older adults with one or more chronic conditions and a multisectoral team of experts in multimorbidity, eHealth, informatics, human factors engineering and health services/KT research to be involved at all stages of KeepWell's design, content and functionality. The older adult working group were recruited from the NYGH Patient and Family Advisory Council (Toronto, Ontario) and the St. Michael's hospital volunteer organisation (Toronto, Ontario) between 2016 and 2017. The KeepWell prototype design and functionality evolved through a series of discussion groups with the patient working group to explore end-user needs (chronic disease management), to determine the 'look and feel' (design, features, functionality and flow) and to review and make key decisions about its content, language and flow. Our clinician partners (geriatricians, family physicians, dietitian and physical activity researcher) helped create the lifestyle recommendations using clinical practice guidelines and focus group discussions 2017–2018. Our e-Health technology partner (QoC Health) used results of a requirements analysis (ie, technical and functional specifications) to develop the software to iteratively programme alpha and beta versions of KeepWell (between 2017 and 2019). The prototype was pilot tested in a usability study between 2018 and 2019 with 20 older adults to ensure that it meets the principles

of good interaction<sup>42–45</sup> and user-centred design.<sup>46</sup> This involved observation of participants as they interacted with the KeepWell prototype, and iteratively addressing errors (after two to three participants) to address errors and to ensure optimised functioning, navigation, content and flow of the tool for older adults.<sup>25</sup>

### OUTCOMES

Table 2 provides the detailed description of all the outcomes organised according to the RE-AIM and Proctor *et al*'s frameworks of implementation evaluation.<sup>27 28</sup>

**Primary outcomes** were perceived self-efficacy for managing identified chronic diseases or risks measured at 6-month follow-up using a validated 6-item, self-efficacy scale<sup>47 48</sup> which is embedded within the HRQ of the KeepWell application. We selected this as our primary outcome because increasing self-efficacy is a prerequisite for behaviour change, which, through improved self-management may influence health and healthcare use.<sup>49</sup> All participants will complete this outcome assessment via the HRQ of KeepWell at baseline, 3-month and 6-month follow-up.

**Secondary outcomes** were (i) self-efficacy at 3-month follow-up; (ii) quality of life<sup>50</sup>; (iii) health background/status (self-reported chronic diseases and risks) collected via the HRQ of KeepWell; (iv) lifestyle (self-reported caffeine and alcohol intake, physical activity,<sup>51</sup> nutrition,<sup>52</sup> smoking and bladder health) collected via the HRQ of KeepWell; (v) social engagement and connections<sup>53</sup>; (vi) eHealth literacy<sup>54</sup>; (vi) acceptability and (vii) appropriateness (measured via survey to intervention participants and interviews with a subsample at the conclusion of the trial).

**Implementation outcomes** were (i) reach (participant rate, representativeness and demographic characteristics); (ii) effectiveness (as described above for primary and secondary outcomes as described above); (iii) adoption (proportion of participants who complete KeepWell tasks such as the HRQ, priority and goal setting; and use KeepWell features such as the wellness vision, lifestyle tracker, progress, menu, journal and resources); (iv) fidelity (rate of process objectives achieved); (v) implementation cost (cost description analysis to assess the total cost of implementing the KeepWell overall and by stage (eg, one-time costs vs ongoing costs such as for web hosting, study personnel time) and (vi) maintenance/sustainability (use of KeepWell over time at baseline, 3-month and 6-month follow-up; as well as 6 months after trial completion).

### Sample size calculation

In their Cochrane review of lay-led self-management interventions, Foster *et al* found 10 studies that looked at self-efficacy and these interventions showed a small, statistically significant improvement (standardised mean difference  $-0.30$ , 95% CI:  $-0.41$  to  $-0.19$ ).<sup>55 56</sup> Using these estimates to calculate our sample size, targeting a power

**Table 2** Outcomes and outcome measures according to the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) and Proctor *et al* frameworks

Outcome domain: outcome	What will be measured	Measure
<b>Reach*</b>		
Rate of involvement of KeepWell participants or the participant rate	Proportion of older adults who participates in the study	Number of participants divided by total number of eligible individuals
Representativeness of the study sample	Similarity or differences between those who participated and those who did not	Comparison of participant demographic characteristics
	Reason for non-participation	Content analysis to understand reason for non-participation
Demographic characteristics	Age, sex	Health Risk Questionnaire (HRQ) of KeepWell
<b>Effectiveness*</b>		
Primary outcome		
Self-efficacy	Change in efficacy from baseline to 6-month follow-up	Stanford Chronic Disease Self-efficacy Scale <sup>47 48</sup> embedded within the HRQ of KeepWell
Secondary outcomes: patient-reported outcomes		
Self-efficacy	Change in efficacy from baseline to 3-month follow-up	Stanford Chronic Disease Self-efficacy Scale <sup>47 48</sup> embedded within the HRQ of KeepWell
Quality of life	Quality of life	EuroQoL (EQ5D) <sup>50</sup> embedded within the HRQ of KeepWell
Health background/status	Self-reported chronic diseases and risks; family history of disease/risks	Collected via the HRQ of KeepWell
Lifestyle	Self-reported caffeine intake, alcohol intake, physical activity, diet, smoking and bladder health	All collected via the HRQ of KeepWell; Nutrition is assessed using the Nutritional Health Checklist <sup>52</sup> ; physical activity assessed using the Rapid Assessment of Physical Activity <sup>51</sup>
Social engagement and connections	Self-reported measure of social engagement including family and friends	Lubben Social Network Scale <sup>53</sup> embedded within the HRQ of KeepWell
eHealth literacy	Self-reported measure of eHealth literacy	The eHealth Literacy Scale for older adults <sup>54</sup> embedded within the HRQ of KeepWell
Secondary outcomes: patient-reported experiences		
Acceptability†	Satisfaction with KeepWell (content, complexity, comfort, delivery, ease of use)	Survey to all intervention participants and one-on-one interviews with a subset of this sample at the conclusion of the trial.
Appropriateness†	Perceived fit, relevance, compatibility, suitability, usefulness, practicability	
<b>Adoption*†</b> <i>(Uptake, utilisation, initial implementation, intention to try; the degree to which KeepWell stimulates the interest or holds the attention of participants: level of interaction)</i>	Number and proportion of study participants who complete KeepWell tasks (HRQ, priority and goal setting) and use KeepWell and its features (wellness vision; lifestyle tracker; tracker progress; menu; journal; resources; instructional videos)	KeepWell website metrics (number of users, hits, tasks completed; time taken to complete each section of KeepWell (tasks) using timed logs of system interactions) including interaction with its features.
<b>Implementation*</b>		
Fidelity† <i>(The extent to which KeepWell was delivered as intended; actual fit, relevance, compatibility, suitability, usefulness)</i>	Rate of process objectives achieved: ▶ Successfully logged into KeepWell ▶ Completed the HRQ at baseline, 3-month and 6-month follow-up ▶ Generated an action plan (priority and goal setting)	KeepWell website metrics (number of users, hits, tasks completed)
Implementation cost†	The cost of implementing KeepWell ▶ Web hosting ▶ Study personnel time to respond to questions and feedback during the study	Documentation of hosting and KeepWell resource costs
<b>Maintenance/sustainability*†</b>		
<i>Extent to which behaviours are sustained 6 months or more after treatment of intervention</i>	Use of KeepWell features over time (baseline, 3-month and 6-month follow-up). We will also collect data on the use of KeepWell for an additional 6 months after the trial completion (intervention group). Participants in the control group will also be given access to KeepWell, so we will collect data on their use as well.	KeepWell website metrics (number of users, hits, tasks completed)

 \*RE-AIM framework constructs.<sup>27</sup>

 †Proctor *et al* framework constructs.<sup>28</sup>

of 0.80 and assuming a dropout rate of 25%, we estimate that 220 older adults are needed per group for a total of 440 participants. In a previous interrupted time series

study, an osteoporosis self-management tool housed in a touch-screen laptop computer was implemented across three primary care practices for 12 months, with a total



of 350 patients who completed the risk assessment questionnaire,<sup>33</sup> so our proposed sample size of 440 patients is feasible, given our patient organisation, hospital and primary care partnerships.

### Data collection and analysis

All participant data from the KeepWell web-based application will be downloaded and stored on a secure cloud-based server of QoC Health, which adheres to Health Insurance Portability and Accountability Act (HIPAA) and Personal Health Information Protection Act (PHIPA) security standards; data will be accessible via Amazon Web Services. Data will be collected at baseline, 3-month and 6-month follow-up with an interim analysis planned at the midpoint of the trial (3-month follow-up). We will provide descriptive statistics, where we will summarise binary and categorical outcomes using frequency and percentages. Means and SD or median and IQRs will be used to summarise continuous outcomes. We will use the  $\chi^2$  or Fisher's exact test to compare binary outcomes and independent two sample t-tests for continuous outcomes. For the primary outcome, a general linear model will be fit to investigate differences between groups in self-efficacy at 6 months. We will adjust for potential confounders (including baseline self-efficacy) and perform subgroup analyses (patient chronic conditions, risk factors, age group (65–74, 75–84, 85+ years), sex and gender). We will perform visual investigation (eg, through scatter plot displays) and analytical outcomes along with logistic regression analyses to determine whether unique patient characteristics predict thresholds of use for different KeepWell components. To examine the change in self-efficacy over time (secondary outcome) between groups (incorporating self-efficacy scores at baseline, 3 and 6 months), we will use a linear mixed-effects model.<sup>57 58</sup>

For the cost description analysis, we will estimate the cost to implement and deliver KeepWell from the public healthcare payer perspective, including an exploration resource costs required (eg, online data collection/analysis, web system testing/hosting). The KeepWell platform collects user data for these measures, so we will be able to track them longitudinally to observe how the solution impacts on outcomes. The findings from the cost description analysis will represent the cost of KeepWell to the healthcare system. All clinical outcomes will be measured at baseline, 3-month and 6-month follow-up and assessed according to intention to treat. All statistical analyses will be carried out using the R statistical software.<sup>59</sup>

### Patient and public involvement

Our patient co-design team consisting of nine older adults were involved in the development of the KeepWell tool. They were also part of our larger stakeholder team (ie, our IKT team) consisting of researchers and clinicians to design and plan our trial and to prepare this protocol. We discussed the objectives and plans for the KeepWell tool development as well as its evaluation via quarterly virtual meetings, phone calls and email. The patient codesign

team will continue to be involved in the conduct of the trial including data analysis and interpretation of our results at 3-month and 6-month follow-up. They will also take an active role in helping to develop optimised strategies to disseminate our results to patients and the public at the conclusion of the study.

### Ethics and dissemination

**Ethics:** Ethical approval has been received from the NYGH Research and Ethics Board (REB) (#20-0007). Any protocol modifications will be reported to the NYGH REB. To ensure data confidentiality, all participant data will be coded using a unique identification number, and all trial results will be presented in aggregate form only and stored securely on the NYGH research server. The final trial data set will be accessible to the principal investigator and the data assessor.

**Dissemination:** We will use a wide range of passive and active end-of-grant KT approaches to disseminate our findings. This will include publications and presentations of our trial results to researchers and clinicians, creating plain language infographics for older adults, the public and community organisations. We will also work with our team to develop more active strategies for disseminating of our findings such as an end-of-grant meeting to discuss results, implications and next steps. In all these strategies, we will ensure that the messages will be clear, simple and tailored to the needs of each audience group, whether these are individuals (physicians, patients, caregivers, policy-makers and researchers) or organisations (eg, the RTO, hospitals), including how they prefer to receive this information.

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