STUDY INFORMATION AND CONSENT

Effectiveness of an eHealth application for older adults with multimorbidity (KeepWell): a hybrid effectiveness-implementation, pragmatic randomized controlled trial
September 2020

STUDY TITLE:
Effectiveness of an eHealth application for older adults with multimorbidity (KeepWell): a hybrid effectiveness-implementation, pragmatic randomized controlled trial

STUDY PRINCIPAL INVESTIGATOR:
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NORTH YORK GENERAL
Research Ethics Board
APPROVED
as of 14-DEC-2020

RESEARCH ETHICS BOARD APPROVALS:
North York General Hospital (NYGH) – Full Board Review & Approval #20-0007

CLINICAL TRIALS REGISTRATION NUMBER:
NCT04437238 (ClinicalTrials.gov)

FUNDER:
This study is funded by the Canadian Institutes of Health Research (CIHR). The development of the KeepWell tool was funded by both CIHR and the Ontario Ministry of Health and Long-term Care.

STUDY PERIOD:
September 2020 to August 2021

BACKGROUND
The burden of chronic disease is a global issue, particularly amongst seniors who are the largest growing proportion of the Canadian population. Almost 4 out of 5 persons aged 65 and older have one chronic condition, while approximately 70% have two or more chronic conditions, which can directly impact a person's quality of life and can put a strain on the healthcare system. Self-management is a process whereby an individual assumes responsibility for their own behaviour and wellness. The concept of self-management has been applied to the setting of chronic disease and is considered an important component of care. Different disease management tools have been developed to support optimal chronic disease self-management. However, most of these tools are of limited benefit, address only one or two chronic diseases, and are not developed for older adults. To address these gaps, we created "KeepWell" (KW), an evidence-based eHealth self-management tool to support older adults with

complex care needs. KeepWell is a patient-centered, multi-chronic disease management tool that incorporates the care for two or more chronic conditions from among the top 10 high-burden chronic diseases (i.e., highly prevalent and associated with significant morbidity and mortality). KeepWell was co-developed with older adults and has undergone usability testing with older adults representative of who it is designed for. We are now ready to evaluate the KW tool more broadly.

How was KeepWell developed?
The Principal Investigator conceived of the idea of the KeepWell tool and worked with a multidisciplinary team of healthcare professionals (e.g., geriatricians, family physicians, nurses, dieticians), our eHealth technology partner (QoC Heath Inc.), patient partners (older adults) and health services researchers to develop it. NYGH was the host site for KeepWell's development including our patient partners who co-designed it; they were recruited from the NYGH Patient and Family Advisory Council (PFAC) group. The patient co-design group played an important part to ensure that the KeepWell tool was designed and developed to meet the needs of its target end-users (i.e., older adults).

This research study was funded by a grant from the Ministry of Health and Long-term Care (MOHLTC), and from the Canadian Institutes of Health Research (CIHR). QoC Health Inc. was paid directly from both of the grants. There were no other commercial entities involved in the design or development of the KeepWell tool.

PURPOSE OF THE KEEPWELL EVALUATION STUDY
We will evaluate the effectiveness, economic impact, and uptake of the KeepWell tool in a 6-month study. The primary outcome of our study is perceived self-efficacy for managing their chronic disease(s) or risks. The findings of this study will be used to improve KeepWell and adapt it for use in other settngs such as primary care. To evaluate KeepWell, we are conducting a randomized controlled trial or an RCT. An RCT involves the random assignment of participants to either an intervention (the KeepWell tool) or control (no KeepWell tool). We are also interested in collecting data to help us to understand (i) the implementation potential and cost of implementing KeepWell and (ii) satisfaction among users based on their experiences in using KeepWell for 6 months.

WHY YOU WERE SELECTED TO PARTICIPATE IN THE KEEPWELL EVALUATION STUDY
You are being invited to participate in this study because you meet the study's eligibility criteria: are aged 65 years or older, have one or more chronic condition (diabetes, heart failure, cardiovascular disease, dementia, chronic kidney disease, osteoporosis, osteoarthritis, rheumatoid arthritis, COPD, depression, urinary incontinence, stroke), have access to a computer or tablet device (e.g., iPad, Android tablet), have an email account, are English speaking, and able to consent based on your understanding of the study and its participation details.

PROCEDURES AND PARTICIPANT RESPONSIBILITIES FOR THIS STUDY
Once enrolled in the study, you will be randomly assigned to one of two groups: (i) the intervention (KeepWell) group or (ii) the control group.

What is the KeepWell intervention?

- KeepWell is a fully functional, standalone eHealth application aimed at supporting the self-management of older adults with multimorbidity.
- KeepWell can be used on any electronic device and has innovative features that most other chronic disease applications don't have:
    i. a multi-disease focus (it can generate lifestyle advice for any combination of the top 10 chronic conditions affecting older adults);
    ii. an avatar health coach that walks users through the tool;

iii. a health risk questionnaire (HRQ) covering three risk dimensions: health (chronic diseases), lifestyle (physical activity, diet, smoking, alcohol, caffeine, bladder health), and social and emotional well-being (social frailty, isolation, loneliness);
iv. an evidence-based Action Plan with lifestyle advice customized to user's risks; and
v. other eHealth self-management tactics that have been shown to improve outcomes (interactive lifestyle tracker, journaling).

- The health coach avatar leads users through a health priority and goal setting exercise that allows them to create a customized action plan based on guideline recommendations for lifestyle changes.
- Users can then put their plan into action through a lifestyle tracking feature that allows them to track their progress in their identified lifestyle areas.
- KeepWell also has an extensive resource library, which has links to additional high-quality health and lifestyle information across topics of interest to older adults (e.g., physical health, mental and emotional health, social health, sexual health, disease-specific).

Once you log into the KeepWell tool, the first thing you will be asked is to review and agree to the "Terms of Use". These are provided at the end of this Study Information and Consent document (Appendix A) for your review now. Once you agree to the "Terms of Use", you will be directed to start using KeepWell.

If you are assigned to the "Intervention Group", your participation will involve:

1. Using the KeepWell tool for 6 months
2. Completing a health risk questionnaire in the KeepWell tool at 3 time points:
    - At the beginning of the study (i.e., your first use of KeepWell)
    - At 3-months follow-up (midway through the study)
    - At 6-months follow-up (end of the study)
3. At the conclusion of your 6-month participation, you will be asked to complete a short online satisfaction survey (approximately 10-15 minutes) based on your experience using KeepWell during your participation.
4. On the last page of the satisfaction survey, you will be invited to participate in a follow-up 1.0hour interview (by phone or virtually) with a member of the study team, to further discuss your experiences and satisfaction in using KeepWell. Your participation in this interview is ***optional***. If you do indicate that you are interested in participating in the interview, you may be randomly selected to participate in the interview. All interviews will take place once the satisfaction survey is completed by all "Intervention Group" participants.

PLEASE NOTE: you won't be able to use KeepWell until you complete the health risk questionnaire at these time points

If you are assigned to the "Control Group", your participation will involve:

1. Completing a health risk questionnaire using an online survey (SurveyMonkey) via an email invitation at 3 time points:
    - At the beginning of the study
    - At 3-months follow-up (midway through the study)
    - At 6-months follow-up (end of the study)

After the conclusion of this study, you will receive a summary of your results and you will be given full access to the KeepWell tool.

The Health Risk Questionnaire
Completing the health risk questionnaire takes approximately 15 minutes. The total time commitment of completing the questionnaire three times (across the 6-month study period) is approximately 45 minutes.

At any time during the course of this study, you are encouraged to discuss and share any questions or comments you may have with your doctor and/or other healthcare provider.

POTENTIAL HARMS AND BENEFITS OF PARTICIPATING IN THIS STUDY
There is little risk or harm associated with participating in this study. Participants in the intervention group will be provided with a summary of their responses to the health risk questionnaire. There is a risk that participants may be upset by these results or perceive them negatively. The KeepWell tool encourages participants to connect with their health care provider throughout the course of their participation in this study and to share their questionnaire results and action plan. As with any online tool or electronic platform, there is always the potential of risk of a breach of confidentiality. However, we have taken careful steps to help mitigate this risk, including security measures in place via our technology partner (QoC Health Inc.), which means that all data will be downloaded and stored on a secure cloud-based server of QoC Health, which adheres to HIPAA and PHIPA security standards. Additionally, the coding of your data and information is done using a unique identification number.

We anticipate several potential benefits for participants in this study. First, participants will have the opportunty to contribute to our understanding of the effectiveness of the KeepWell tool for managing their identified chronic disease(s) or risks and how to optimize their health through lifestyle changes. Second, through their interactions with KeepWell, participants will receive evidence-based information and recommendations about their chronic conditions and/or health risks and how to respond to these with self-management tools embedded in the KeepWell tool. Additionally, participants will receive guidance through the health coach avatar built into KeepWell, which allows them to set a wellness vision and goals to address 1-2 lifestyle areas of their choice. Their goals and subsequent actions are at their discretion, and can result in maintaing or improving their wellness.

PARTICIPATION AND WITHDRAWAL
Participation in this study is entirely voluntary. You can withdraw your participation at any time, which will not result in any negative consequences. If you wish to withdraw from the study for any reason or at any time, simply indicate your request to withdraw by either calling (416-209-4055) or emailing the Study Research Coordinator, Julie Makarski at julie.makarski@nygh.on.ca . We will use your data up to and including the date of your withdrawal.

ADDITIONAL INFORMATION: PRIVACY & CONFIDENTIALITY
The information you provide through your participation will be kept strictly confidential, and your individual responses will be combined with those of other participants, which means that your individual responses will not be linked to you; all your data will be kept strictly confidential. Unless otherwise required by law, the results of this study will only be seen by the study team and the REB of North York General Hospital (Toronto, ON, Canada) for the purposes of study monitoring and to oversee the ethical conduct of this research. Any identifiable information disclosed during the randomized controlled trial will be separated. To ensure privacy and confidentiality, you will be assigned a unique identification number. Further, all findings will be presented in aggregate form only, so as to keep individual responses confidential. The trial results will be stored securely on the North York General Hospital

research server. Responses will be accessible by the principal investigator and study team, and will be destroyed seven years after the publication of this work. It is important for you to understand that despite these protections, there may still be a risk of unintentional release of information. However, any chance that this information will be accidentally released is very small.

CONSENT PROCESS

You are asked to review the information contained in this study information and consent document and to consider your interest and availability to participate in this study. You may take up to 1 week to review this document and to decide whether or not to participate. If you wish to participate, you will be asked to provide your consent to participate verbally, ***over the phone,*** with the study coordinator, or with another member of our research team ("KW RCT Enrolment Phone Call"). As part of your consent, we will also specifically **request your consent to use your email address** for the duration of this study period (e.g., to email you reminders regarding your participation) and to communicate with you through the KeepWell tool (e.g., when you use the "Ask for Help" feature in KeepWell). A copy of this study information and consent form document completed with your consent will be emailed to you for your records (via the "KW RCT Enrolment Email"). Before we send you the "KW RCT Enrolment Email", we will send you a "Test Email" to ensure that we have your email address correct. **You will be asked to reply to this "Test Email" to confirm that we in fact have your correct email address**. This step in the enrolment process is important to protect your privacy and confidentiality of the information we will be emailing you. When we receive your email reply to the "Test Email", we will then send you the official enrolment email. Depending on which study group you are randomly assigned to, the "KW RCT Enrolment Email" will include the following:

Intervention (KeepWell) group:

- Your unique KeepWell username (Login ID)
- KeepWell website address
- Copy of the completed "Study Information and Consent Form" document (as an attachment)
- KeepWell Tip Sheet (as an attachment)
- and username (not password) and the "KeepWell Tip Sheet" for those in the intervention group; a link to the health risk questionnaire for those in the control group.

Control group:

- A link to the online health risk questionnaire
- Copy of the completed "Study Information and Consent Form" document (as an attachment)

Lastly, please note that your consent will be reaffirmed with the completion of your participation in this study. If you have any questions at any time about this study or the consent process, please do not hesitate to contact Julie Makarski, the KeepWell RCT Study Research Coordinator, by phone (416-209-4055) or email (julie.makarski@nygh.on.ca).

CONTACT INFORMATION

Who to Contact if You Have any Questions

If you have any questions about this study or your participation, you may contact Dr. Monika Kastner, the Principal Investigator of this study (monika.kastner@nygh.on.ca) or Julie Makarski (julie.makarski@nygh.on.ca or 416-209-4055), Study Research Coordinator, at North York General Hospital.

Research Ethics Board Office Contact Information
If you have any questions regarding your rights as a research participant, you may contact the Office of Research Ethics of North York General Hospital by phone (416-756-6444, ext. 3485) or email (reb@nygh.on.ca), during regular business hours.

Thank you for your time and we look forward to receiving your input.
Sincerely,

Monika Kastner, PhD
Principal Investigator, KeepWell RCT Study

Study Team:

Role	Name	Email Address	Site
Principal Investigator (Study Lead)	Dr. Monika Kastner	monika.kastner@nygh.on.ca	NYGH, Office of Research & Innovation
Study Research Coordinator	Ms. Julie Makarski	julie.makarski@nygh.on.ca	NYGH, Office of Research & Innovation
Study Research Assistant	Ms. Kithara Manawadu	kithara.manawadu@nygh.on.ca	NYGH, Office of Research & Innovation

STUDY INFORMATION AND CONSENT DECLARATION

Effectiveness of an eHealth application for older adults with multimorbidity (KeepWell): a hybrid effectiveness-implementation, pragmatic randomized controlled trial

September 2020

STATEMENT OF CONSENT:

I have read and/or discussed, and understood the information contained in the "Study Information and Consent" document for the *"Effectiveness of an eHealth application for older adults with multimorbidity (KeepWell): a hybrid effectiveness-implementation, pragmatic randomized controlled trial"* (the KeepWell RCT Study).

Any questions I may have had have been adequately answered by a member of the study team.

Respondent Name:

Date:

Person obtaining consent - Name:

Person obtaining consent - Signature:

CONSENT DECLARATION – VERBAL, OVER THE PHONE:

The Respondent has declared their consent as follows:

- ❍ Yes, I consent to participate in the KeepWell RCT Study
- ❍ No, I do not consent to participate.

Consenting Participants:

For those who consent to participate, please consent to obtaining your email address:

- ❍ "I agree to share my email address with the KeepWell Study research team for use during the study, and for the purposes of updating my email via KeepWell, which will allow me to communicate with the KeepWell Study research team"

Non-Consenting Respondents:

For those who do not consent to participate, we would like to request their consideration to disclose their reason for not participating. Information regarding non-participation will be invaluable to inform the knowledge (evidence) base and to advance the science of recruiting older adults to participate in research given the importance of ensuring patient-centred care.

Thank you for your consent declaration. Would you consider providing your reason for not participating in this study, by selecting ONE option from this list that best describes your reason:

- ❍ Study not relevant
- ❍ Study not of interest
- ❍ I do not have time to participate
- ❍ I have a language barrier
- ❍ I have a technology barrier
- ❍ Prefer not to say
- ❍ Other: Please briefly describe

APPENDIX A. KeepWell's Terms of Use (included here for *"information purposes only"*)

Disclaimer

KeepWell and its affiliates use reasonable care in providing information and resources. However, KeepWell does not guarantee that the information or resources are up to date, accurate or complete. If you find an error, please notify keepwell@nygh.on.ca.

KeepWell services are provided "as is" with no warranty, express or implied, including, without limitation, warranties of merchantability or fitness for a particular purpose. KeepWell assumes no liability for any loss or damage for errors or omissions in its services whether arising in contract, negligence or otherwise. KeepWell does not warrant that the functions contained in the materials will be uninterrupted or error-free, that defects will be corrected or that this site or the server that makes it available are free of viruses or other harmful components.

Under no circumstance will KeepWell be liable for any loss or damage caused by a user's reliance on information obtained through KeepWell. The information provided on this website is for educational purposes only and should not be treated as legal, financial, medical or any other form of advice. It is the user's responsibility to evaluate the usefulness, accuracy and completeness of any information, resources or any other content available through KeepWell. KeepWell is designed to help individuals better understand their health and make lifestyle choices. Information in KeepWell is not intended to be considered or relied upon as medical advice or a substitute for medical advice. You are responsible for obtaining appropriate medical advice from a physician or other qualified healthcare professional prior to acting upon any information available through KeepWell.

Privacy Statement

The Internet is not a completely secure environment. KeepWell treats all communications in a confidential manner. Please read the following policy to understand how your personal information will be used when you utilize our services.

Security

Unfortunately, data transmission over the Internet is not completely secure. While we try to protect your personal information, we cannot guarantee the security of any information you transmit to us, and you do so at your own risk.

Your account is password protected. We highly recommend that you do not disclose your password to anyone. You are responsible for maintaining the secrecy of your password(s). We will not request your password in an unsolicited phone call or e-mail.

Remember to log out of your account and close your browser window when you have finished. This helps prevent others from accessing your personal information and correspondence.

Registration

When you register to receive services from KeepWell we may require you to submit personal information. This data is used by KeepWell to provide you with a unique experience tailored to your personal issues and to communicate with you when you request information, as well as inform you of new products or changes to products and services. If your personal information changes at any time, KeepWell will provide you with a way to correct or update or remove the personal information you give us. We will not intentionally disclose your personally identifiable data to third parties without your permission. However, personally identifiable information may be disclosed when required by law or if it becomes necessary to bring legal action against someone who has violated the terms and conditions of this site.

IP Addresses

KeepWell will collect IP addresses for systems administration, to report aggregate information, to troubleshoot problems and to audit and improve the use of our Website. We will use IP addresses to identify a user only when necessary to enforce compliance with our terms of service or to protect our service, site, customers or others.

Partnerships

Please be aware that certain content providers may have privacy policies and terms of use that are separate and distinct from the policies set forth on the KeepWell Online Terms of Use page. In addition, it is possible that a content provider may use cookies.

Links

KeepWell provides links to other Internet sites only for informational purposes and for the convenience of its users. When users select a link to an external website, they are leaving the KeepWell website and are subject to the privacy and security policies of the owners/sponsors of the external site.
KeepWell does not endorse organizations that sponsor linked, external websites and not endorse the views they express or the products or services that such organizations may offer. KeepWell does not control or guarantee the currency, accuracy, relevance, timeliness or completeness of information found on linked, external websites.

KeepWell cannot authorize the use of copyrighted materials published on linked, external websites. Users must request such authorization from the sponsors of those linked websites.

Usage-Related Information

This is information that we log about KeepWell usage. For example, it could include:

- IP addresses of a computer or device
- Statistics such as how often and for how long users visit KeepWell
- Browser information or other application used
- Operating system of the computer or device
- Logs of which activities users perform using KeepWell (e.g., viewing and completing challenges) and the outcomes of those activities (e.g., rewards won)

We use usage-related Information to manage our business and operations and to track usage and for security purposes. We may retain Usage-Related Information indefinitely. KeepWell web server administrators may produce summary reports from these logs and share that information with content managers. We typically use this information in aggregate to understand what pages are popular, how users are navigating to and within the site and when the site is used most frequently. While information in server logs generally cannot be used to identify individuals, you should be aware that such information may be captured. To protect your privacy, please do not send us confidential information by email.

Use of tool

By using the KeepWell tool, you are agreeing that you understand and agree to this disclaimer.

- ○ Yes, I agree with the Terms of Use
- ○ No, I do not agree with the Terms of Use