Research Protocol

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The use of information and communication technologies by arthritis health professionals to disseminate a self-management program to patients: a pilot randomized controlled trial protocol

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Abstract

Design and objective: This paper describes the protocol for a three-arm, single-blind, parallel design randomized controlled trial (RCT) to investigate the perceived usability of Facebook to share information from an evidence-based arthritis self-management program with patients compared with email or an educational website after two weeks.

Study population: Three-hundred and twenty-seven arthritis health professionals (i.e., nurses or physical/occupational therapists) registered with their regulatory body in Canada, currently practicing clinically defined as spending a minimum of 50% of their time (working week) in direct arthritis patient care.

Interventions: The proposed RCT will include three information and communication technology (ICT) intervention groups: Facebook, email, and an educational website.

Outcome measures: The primary outcome will be perceived usefulness by health professionals of using the ICT intervention to share information with their patients according to the technology acceptance model 2 (TAM2) questionnaire at two weeks post-intervention. Secondary outcomes will include other usability domains of the TAM2 questionnaire (i.e., perceived ease of use, result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use) at two weeks, three months, and six months post-intervention.

Analysis: An analysis of variance will be conducted to compare TAM2 questionnaire scores of the Facebook group with the email and educational website groups.

Keywords

Social media, dissemination, osteoarthritis, rheumatoid arthritis, self-management, information and communication technologies

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Introduction

The transfer of research knowledge into clinical practice remains a challenge among health professionals and researchers,[1] resulting in ineffective implementation of clinical practice guidelines (CPGs).[2] McGlynn et al. revealed that approximately only 55% of osteoarthritis patients in the United States received

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recommended care.[3] Harold et al. correspondingly concluded that a significant number of rheumatoid arthritis patients do not receive care that is consistent with current arthritis recommendations.[4] There is therefore a need to improve the knowledge-to-action gap among the appropriate stakeholders. The process of implementing knowledge into action is known as knowledge translation (KT).[5] Online KT resources, such as information and communication technologies (ICTs), can provide health professionals and consumers with an additional platform to disseminate and access CPGs.[6,7] ICTs are defined as "technologies that provide access to information through telecommunications focusing primarily on communication technologies including the Internet and wireless networks, cell phones, and other communication mediums".[8]

Patients are able to manage their chronic conditions when traditional patient education is complemented by self-management support and when information and technical skills to identify problems are provided by health professionals.[9] Examples of self-management support techniques for patients include enlisting social support, determining goal achievement, providing personalized feedback, and the creation of small actions plans and goal setting.[10] There is a pressing need for the promotion of evidence-based arthritis self-management support by health professionals with their patients, as one in five Canadians has reported having arthritis, and an estimated 23.8% of the population will have arthritis by 2035.[11]

People Getting a Grip on Arthritis (PGrip)[12] is a bilingual (English/French), educational, evidence-based online self-management program for patients with rheumatoid arthritis (RA) and osteoarthritis (OA) based on Ottawa Panel CPGs (2004–2017). The program is based on findings from randomized controlled trials (RCTs) that assessed the efficacy of various self-management interventions among patients with arthritis. The study findings were then synthesized through systematic reviews and graded by the Ottawa Panel.[13–18] Rigorous methods were then used to develop the Ottawa Panel CPGs for the self-management of RA and OA.

A recent systematic review that identified research on health professionals' perceived usability and practice behavior-change using ICTs to disseminate CPGs concluded variable findings by type of ICT.[19] However, the heterogeneity between studies did not allow for a clear comparison, and the paucity of properly conducted studies did not provide a strong conclusion on the effectiveness of ICTs as a dissemination strategy for CPGs.[19] Thus, to address the knowledge gap of determining which ICTs are perceived as having the greatest usability among health professionals, a high-quality, randomized comparative study is therefore needed.

Hypothesis and objectives

The general hypothesis of the proposed RCT is that arthritis health professionals will demonstrate greater perceived usability with Facebook to share information from the PGrip program with patients compared with email or an educational website after two weeks. Usability is the behavior intention to use a system as determined by its perceived usefulness and perceived ease of use.[20] The primary research question presented below will address the comparative differences between the three ICT interventions for one component (i.e., perceived usefulness) of perceived usability according to the technology acceptance model (TAM2). The secondary research question will address the comparative differences for other components of usability according to TAM2 (i.e., perceived ease of use, result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use).[20] Further secondary and exploratory research questions are described in Table 1.

Methods

This study will be guided by one of the milestones of the knowledge-to-action Framework.[5] Specifically, this study will address the "select, tailor, and implement interventions" milestone as the objective described above will assess strategies to disseminate the evidence-based PGrip self-management educational program. The findings of this study will be reported in concordance with the CONSORT-EHEALTH checklist.[21]

Study design

A three-arm, single-blind, parallel design RCT will be conducted to assess the three ICT interventions (dissemination strategies). The total observation period will be six months, with follow-up assessments taking place at two weeks, three months, and six months following the delivery of each intervention. The study participants will have access to the online material for the complete duration of the study. Given the nature of the ICT interventions, blinding of study participants is not possible. However, the research coordinator and investigators will be blinded to participants' intervention allocation. All communication (e.g., automated email reminders to complete online questionnaires will be generic (i.e., no specific mention of which ICT) to ensure blinding in maintained.

Recruitment

Participants will be recruited over a two-month duration. Study participants will be recruited across Canada by online advertisements using email or online newsletters from arthritis health professional organizations (e.g.,

Table 1. Study research questions.

Primary research question
1. Do arthritis health professionals demonstrate greater **perceived usefulness** with Facebook to share information from the PGrip program with patients compared with email or an educational website after two weeks?
Secondary research questions
2. Do arthritis health professionals demonstrate greater **perceived ease of use** with Facebook to share information from the PGrip program with patients compared with email or an educational website at two-week assessment?
3. Do arthritis health professionals demonstrate greater improvements in **other usability outcomes** (i.e., result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use) with Facebook to share information from the PGrip program with patients compared with email or an educational website at two-week assessment?
4. Do arthritis health professionals demonstrate greater **perceived usability** (i.e., as measured by TAM2 domains: perceived usefulness, perceived ease of use, result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use) with Facebook to share information from the PGrip program with patients compared with email or an educational website at three-month and six-month assessments?
Exploratory research questions
5. Do arthritis health professionals demonstrate greater **perceived ease of use** over time (two weeks compared with three months or six months) with either Facebook, email or an educational website to share information from the PGrip program with patients?
6. Do arthritis health professionals demonstrate greater **perceived usability** (i.e., as measured by the System Usability Scale, SUS) with Facebook to share information from the PGrip program with patients compared with email or an educational website at two-week, three-month, and six-months assessments?
7. What **perceived barriers** (as identified by the Theoretical Domains Framework [TDF]) are associated with using Facebook, email or an educational website to share information from the PGrip program with patients at two-week, three-month, and six-month assessments?
8. How often do arthritis health professionals **actually use** Facebook, email or an educational website to share information from the PGrip program with patients at two-week, three-month, and six-month assessments?

Arthritis Health Professions Association, The Arthritis Society, Canadian Physiotherapy Association, Canadian Association of Occupational Therapists, and Canadian Nurses Association). The advertisements will include an email address in which participants can inquire about and register to participate in the study. To ensure eligibility criteria are met prior to randomization, participants will be asked to complete an online admission questionnaire. If participants meet the eligibility criteria, they will then be sent an electronic invitation letter by email, which will also include and require informed consent to be acknowledged. After obtaining informed consent, participants will then be invited to complete the baseline questionnaire. All participants will begin the study at the same time. This recruitment process has proven to be successful in a previous feasibility study.[22] Similar recruitment methods used in the feasibility study were approved by the University of Ottawa Research Ethics Board.

Feasibility

For this proposed RCT, we anticipate similar compliance rates as in our feasibility study.[22] All participants completed the baseline questionnaire, while 76 of 78 participants (97.4%) completed the questionnaire at two weeks follow-up, and 75 of 78 participants (96.2%) completed the final questionnaire at three months follow-up. Participants were considered drop-outs if they indicated they no longer wished to continue in the study.

Inclusion criteria

In order to be eligible to participate in this study, participants must meet the following criteria: (a) trained as a nurse or physical/occupational therapist; (b) registered with their provincial professional regulatory body; (c) currently practicing clinically defined as spending a minimum of 50% of their time (working week) in direct arthritis patient care; (d) has Internet access; (e) is computer literate; (f) communicates in English; and (g) did not participate in the feasibility study (including the Advisory Committee). Individuals not meeting all inclusion criteria will not be deemed eligible for the study.

Participant allocation

Health professionals will be randomly assigned to one of three intervention groups based on a sequence of computer-generated random numbers using a blocking factor (randomly varying between 6 and 9). A research coordinator will contact potential participants and will confirm their eligibility after they register for the study via email. Once participants have been deemed eligible and have provided consent, they will be randomly allocated to one of the three intervention groups using the central randomization scheme by a data manager at the research study Methods Center. The data manager will document the participants' initials (first and last) as well as their date of birth (month and year) before running the randomization program. To ensure concealment of allocation, the data manager will document the intervention assignment and assign a study identification (ID) number after running the randomization program. This information will then be provided to a research assistant not involved in data collection. Participants will then be informed by email as to their group assignment following randomization.

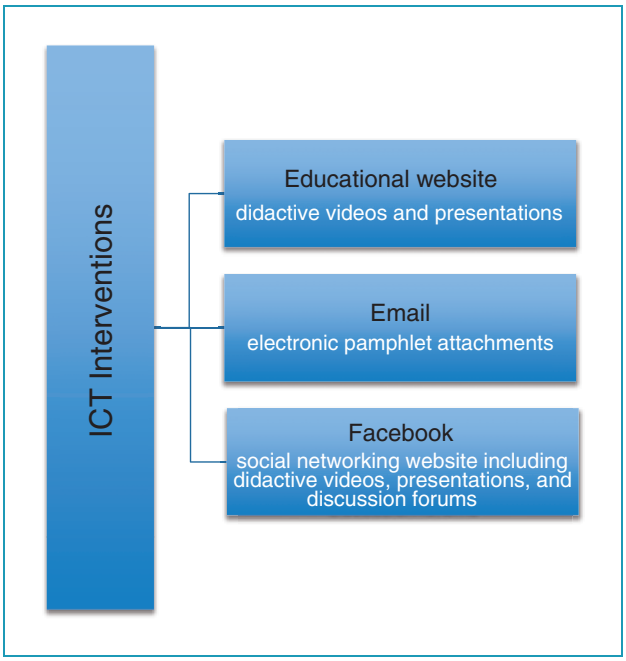

Figure 1. Proposed ICT intervention groups.

Intervention

The proposed RCT will include three ICT intervention groups (Figure 1), in which the PGrip program will be provided online to participants. Similar methodology used in the feasibility study has been approved by the University of Ottawa Ethics Committee (certificate number: H11-12-10).

Educational website (the Arthritis Society website)

The PGrip educational website by the Arthritis Society (TAS) includes a collection of evidence-based self-management videos and slide presentations for OA and RA. The didactic videos are based on knowledge from the Ottawa Panel CPGs, which have been translated into lay terms and tailored for the PGrip program. The self-management interventions presented in PGrip were those that achieved positive recommendations (Grades A, B, and C+) in the Ottawa Panel CPGs.[13–18] According to the Ottawa Panel grading recommendations, a Grade C+ is considered positive and acceptable as it signifies 20% in clinical importance although the finding may not be statistically significant ($p < 0.05$). The self-management intervention videos for OA include: ice massage, hand exercises, aquatic therapy exercises, weight management, and a stationary bicycling program. The RA self-management interventions include: insoles and footwear, yoga, Tai Chi, aquatic jogging, wrist orthotics, and transcutaneous electrical nerve stimulation. For each self-management intervention, two video presentations were created: (a) a narrated PowerPoint presentation of simplified instructions on how to perform/apply the self-management intervention with case scenarios illustrating the appropriateness and relevance of each; and (b) practical sessions with an arthritis health professional providing step by step instructions while performing/applying the self-management intervention with a patient. Participants in the educational website group will be emailed a link to the TAS PGrip website, and will be provided instructions on accessing the didactic videos.

Email (electronic pamphlets)

Participants in the email group will be provided with electronic TAS educational pamphlets on general self-management interventions for OR and RA. The educational pamphlets will be emailed directly to participants as portable document format (PDF) attachments and will contain the same content as the information provided in the PGrip didactic videos described above. Participants will be emailed once for the entire duration of the study, and will not be provided with the links to the TAS PGrip website link or PGrip Facebook group page.

Facebook (social networking website)

Participants in the Facebook group will be provided a link to the PGrip Facebook group page. The group page will include all videos of the presentations from the TAS PGrip educational website. On the group

page, the videos will be clearly labeled and categorized by type of arthritis (i.e., OA or RA) and type of video (i.e., narrated presentation or practical session), to simplify access. The group page also allows for a discussion forum as users can post comments or questions under each video. Other information on the group page will be provided, including an "About" section that provides a brief description of the PGrip program, and a web link to the Arthritis Society's PGrip website. Participants will be provided with instructions on how to access the videos and how to post comments or questions. The primary difference between the Facebook intervention and the comparator interventions is that Facebook is a social media tool that allows for interaction between patients and health professionals by means of sharing information, thoughts, and opinions. The website and email interventions do not include components that allow for interaction between stakeholders.

Outcome measures

Four different measurement assessments will be conducted throughout this RCT for each participant in all three ICT intervention groups (Table 2 and Figure 1). All assessment will be conducted using SurveyMonkey, an online questionnaire platform.[23] The questionnaire links will be sent to participants by email. Participants will be given two weeks to complete each questionnaire, and will be sent a reminder email one week after being provided each questionnaire. For participants in the Facebook group, a reminder message to complete questionnaires will also be posted on the "wall" of the group page. The first assessment will include baseline measurements prior to participating in the ICT interventions. Findings from the questionnaires will be reported using the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).[24]

Monetary compensation (CAN$30.00) in the form of a gift card will be provided to participants for each completed questionnaire as an incentive to complete measurement assessments. This approach was adopted and successful in the feasibility study.[22] In order to receive this compensation, participants will need to provide their mailing address and consent to use this personal information.

The outcome measures will be assessed at two weeks following the delivery of the PGrip program via the various ICT interventions, and at three- and six-month follow-up to determine whether effects are maintained (Table 2). The two-week assessment will be considered the primary endpoint, a time frame that was considered by the study authors to be sufficient to detect differences in usability and has subsequently been confirmed in the feasibility study as statistically significant improvements in usability from baseline were demonstrated.[22] Measurements at three- and six-month follow-up will be considered secondary endpoints for this study. Participants who are unable to complete two consecutive assessments will be considered lost to follow-up.

Primary outcome

Perceived usefulness (TAM2, two weeks post-intervention).

Usability outcomes will be guided by TAM2,[20] which illustrates that behavior intention to use a system is determined by its perceived usefulness and perceived ease of use. The primary outcome of this proposed RCT will be one component of usability: perceived usefulness. Perceived usefulness is defined by Venkatesh and Davis[20] as "the extent to which a person believes that using the system will enhance his/her job performance" (p. 187). The perceived usefulness of each ICT as

Table 2. Assessment schedule and outcome measures.

Assessment	Admission	Baseline	2 weeks post-intervention	3 month follow-up	6 month follow-up
Informed consent (pre-admission)	•				
Demographics	•				
Perceived Usability (TAM2 questionnaire)		•	•	•	•
Perceived Usability (SUS)		•	•	•	•
Barriers (TDF)			•	•	•
Actual Use			•	•	•

SUS = system usability scale; TAM2 = technology acceptance model 2; TDF = theoretical domains framework.

a dissemination strategy for the PGrip program with patients will be measured using an instrument based on the TAM2 questionnaire, a validated tool showing internal consistency reliability and construct validity (20). The TAM2 questionnaire contains 26 items consisting of nine domains: perceived usefulness (four items), perceived ease of use (four items), intention to use (two items), subjective norm (two items), job relevance (two items), output quality (two items), voluntariness (three items), image (three items), and result demonstrability (four items). The TAM2 questionnaire is measured on a seven-point Likert scale (1 = strongly disagree to 7 = strongly agree). A tailored 24-item TAM2 questionnaire was used and piloted in the feasibility study as Facebook may not be accessible due to firewalls in the workplace for all study participants, thus two items from the image domain were removed. The modified TAM2 questionnaire can be found in Appendix 1: Tailored technology acceptance model 2 (TAM2) questionnaire.

Secondary outcomes

Perceived ease of use (TAM2, two weeks post-intervention). Another component of usability, as per the TAM2, is perceived ease of use. Perceived ease of use is defined by Venkatesh and Davis as "the extent to which a person believes that using the system will be free of effort" (p. 187).[20] Similar to the primary endpoint, perceived ease of use will be measured by the tailored TAM2 questionnaire at two weeks post-intervention.

Other usability domains (TAM2, two weeks post-intervention). Other usability domains as per the TAM2 such as result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use will be assessed at two weeks post-intervention using the tailored TAM2 questionnaire.

Other usability time points. TAM2 usability domain scores (perceived usefulness, perceived ease of use, result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use) will also be assessed at three- and six-month follow-up using the tailored TAM2 questionnaire. TAM2 usability domain scores (perceived usefulness, perceived ease of use, result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use) at two weeks post-intervention will be compared with scores at three- and six-month follow-up (change over time).

Exploratory outcomes

The following exploratory outcomes will also be assessed:

- Usability measured by the System Usability Scale (SUS)[25] at two weeks post-intervention and at three- and six month follow-up. The SUS is an empirically validated 10-item questionnaire with five responses from 1 = Strongly disagree to 5 = Strongly agree.[25]
- Perceived barriers to using Facebook, email, or an educational website to share information from the PGrip program with patients at two weeks post-intervention, and at three- and six month follow-up. Participants will be asked to identify their top three barriers to engaging in the ICT intervention as a tool to share information from the PGrip program with their patients. Each identified barrier will be coded and categorized according to constructs of the Theoretical Domains Framework (TDF).[26] This measurement of barriers was also conducted in the feasibility study.[22]
- Actual use of the ICTs to share information from the PGrip program with their patients. Participants will be asked to rank the number of times they used the ICT using a five-point Likert scale ranging from 1 (>8 times) to 5 (0 times). This measurement of actual use was also posed in the feasibility study.[22]

Statistical methods

Data analysis will be conducted on an intention-to-treat basis using SPSS21 software. The multiple imputation technique will be used to adjust for missing data. Baseline characteristics of included participants in all three ICT intervention groups (Figure 1) will be summarized using descriptive statistics (e.g., proportions, means, and standard deviations). To ensure no differences among the ICT intervention groups, baseline characteristics will be assessed and compared.

For the primary outcome (perceived usefulness at two weeks post-intervention), an analysis of variance (ANOVA) will be conducted to compare TAM2 questionnaire scores of the Facebook group with the email and educational website groups. Specifically, Tukey's honest significant difference test will be used in conjunction with the ANOVA to determine whether the means of the primary outcome measure between the three ICT groups are different from each other. As a sensitivity analysis for assessing the robustness of the primary analysis, for any important baseline prognostic variables that are found to be clinically significantly imbalanced between the treatment groups at baseline (e.g., age, sex, disease severity, disease duration), the

ICT intervention groups will be compared, adjusting for these baseline variables using multiple regression; this is in alignment with the European Medicines Agency/Committee for Medicinal Products for Human Use (EMA/CHMP) guideline on adjustment for baseline covariates in clinical trials.[27]

If the underlying distribution is not normal then the nonparametric procedure Kruskal–Wallis one-way analysis of variance will be conducted and the Mann–Whitney test will be used for pairwise comparisons with a Bonferroni correction for multiple testing. If adjustment for baseline variables is needed then the nonparametric method of Wang and Akritas[28] will be used.

For secondary outcomes (perceived ease of use, result demonstrability, output quality, job relevance, image, voluntariness, subjective norm, and intention to use), a similar approach to the primary outcome will be used to compare TAM2 scores of the Facebook group with the email and educational website groups at two weeks post-intervention. These analyses will also be conducted for the following exploratory outcomes: TAM2 usability outcomes at three- and six-month follow-up and SUS scores at two weeks post-intervention, three-month, and six month follow-up. Interpretation of both usability measurements (TAM2 and SUS) will be compared with each other to determine whether both tools are concordant, and a measure of correlation (Spearman's correlation) will be calculated.

To investigate the exploratory outcome of change in TAM2 scores over time from baseline, two weeks post-intervention, three-month and six-month follow-up, a two-way repeated measures ANOVA will be conducted involving the within-factor time (0, 2 weeks, 3 months, 6 months) and between-factor (ICT intervention), following a similar strategy as outlined above for the primary outcome measure.

For the remaining exploratory outcomes of perceived barriers and actual use, findings will be analyzed descriptively using proportions.

Sample size

The following sample size was calculated using the PASS software based on methodology by Desu and Raghavarao.[29] In a one-way ANOVA study, samples sizes of 109 for each group are obtained from the three intervention groups (website, email, and Facebook) whose means are to be compared. The total sample of 327 subjects achieves 80% power to detect differences among the means versus the alternative of equal means using an F-test with a 0.05 significance level. Based on findings from the feasibility study,[22] the common standard deviation of the primary outcome within a group is assumed to be 0.39. Given that a minimally important difference for the primary outcome using the TAM2 questionnaire remains unknown from a clinical standpoint, a small effect size (0.2) based on Cohen's d was deemed to be reasonable by consensus from users of the TAM2 questionnaire. Thus a minimally important difference of 0.8 was considered for this study. To account for a potential loss to follow-up, the sample size has been adjusted to accommodate a 5% loss to follow-up, a conservative estimate compared with the feasibility study (3.8%).[22]

Data sharing

All datasets will be made available from the corresponding author following the completion of analyses, on reasonable request.

Dissemination

The study findings will be written by the research team for publication in academic peer-reviewed journals. Findings will also be made available in lay summary format for various arthritis professional and patient organization websites and newsletters.

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Contributorship: GD, LB and GW conceived the study. GD is the principal investigator. All other authors contributed to the writing and revision of the protocol.

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Appendix 1: Tailored technology acceptance model 2 (TAM2) questionnaire

Domain Item #	1 Strongly disagree	2 Moderately disagree	3 Somewhat disagree	4 Neutral (neither disagree or agree)	5 Somewhat agree	6 Moderately agree	7 Strongly agree
Intention to Use							
1	Assuming I have access to the (ICT intervention) group page, I intend to use it with patients						
2	Given that I have access to the (ICT intervention) group page, I predict that I would use it with patients						
Perceived Usefulness							
3	Using the (ICT intervention) may improve my performance in my job						
4	Using the (ICT intervention) in my job may increase my productivity						
5	Using the (ICT intervention) may enhance my effectiveness in my job						
6	I find the (ICT intervention) may be useful in my job						
Perceived Ease of Use							
7	My interaction with the (ICT intervention) is clear and understandable						
8	Interacting with the (ICT intervention) does not require a lot of my mental effort						
9	I find the (ICT intervention) easy to use with patients						
10	I find it easy to get to the (ICT intervention) to do what I want it to do						
Subjective Norm							
11	People who influence my behavior think that I should use the (ICT intervention) with patients						
12	People who are important to me think that I should use the (ICT intervention) with patients						
13	My use of the (ICT intervention) with patients is voluntary						
14	My supervisor does not require me to use the (ICT intervention) with patients						
15	Although it might be helpful, using the (ICT intervention) with patients is certainly not compulsory in my job						
Image							
16	People in my organization who use the (ICT intervention) with patients have more prestige than those who do not						
Job Relevance							
17	In my job, usage of the (ICT intervention) with patients is important						
18	In my job, usage of the (ICT intervention) with patients is relevant						

(continued)

Continued

Domain Item #	1 Strongly disagree	2 Moderately disagree	3 Somewhat disagree	4 Neutral (neither disagree or agree)	5 Somewhat agree	6 Moderately agree	7 Strongly agree
Output Quality							
19	The quality of the output I get from the (ICT intervention) is high						
20	I have no problem with the quality of the (ICT intervention) output						
Result Demonstrability							
21	I have no difficulty telling others about the results of using the (ICT intervention) with patients						
22	I believe I could communicate to others the consequences of using the (ICT intervention) with patients						
23	The results of using the (ICT intervention) with patients are apparent to me						
24	I would have no difficulty explaining why using the (ICT intervention) with patients may or may not be beneficial						

Source: adapted from Venkatesh V and Davis FD. A theoretical extension of the Technology Acceptance Model: four longitudinal field studies. *Manage Sci* 2000;46:186–204.