An integrative review of chronic illness mHealth self-care interventions: Mapping technology features to patient outcomes

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Abstract
Mobile health (mHealth)—hand-held technologies to address health priorities—has significant potential to answer the growing need for patient chronic illness self-care interventions. Previous reviews examined mHealth effect on patient outcomes. None have a detailed examination and mapping of specific technology features to targeted health outcomes. Examine recent chronic illness mHealth self-care interventions; map the study descriptors, mHealth technology features, and study outcomes. (1) Information extracted from PubMed, CINAHL, and Web of Science databases for clinical outcomes studies published 2010–January 2020; and (2) realist synthesis techniques for within and across case analysis. From 652 records, 32 studies were examined. Median study duration was 19.5 weeks. Median sample size was 62 participants. About 47% of interventions used solely patient input versus digital input; 50% sent tailored messages versus generic messages; 22% augmented the intervention with human interaction. Studies with positive clinical outcomes had higher use of digital input. Software descriptions were lacking. Most studies built interventions: only two incorporated target audience participation in development. We recommend researchers provide sufficient system description detail. Future research includes: data input characteristics; impact of augmentation with human interaction on outcomes; and development decisions.

Keywords
cellular phone, smart phone, clinical trial, patient self-care, home care and e-health, patients with chronic illness or special needs

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Introduction

Chronic disease, with its high prevalence, increased mortality, and associated health costs, is a public health burden internationally.¹ For example, in the United States, the chronic illness cost burden was estimated at 78% of total health care spending.² People living with chronic conditions have economic challenges including medication related costs and reduced ability to work.³ A technology category with significant potential to address this need is mobile health (mHealth)—application of mobile (e.g. hand-held) technologies to address health priorities.⁴ Accordingly, mHealth studies have been published, among which are behavioral interventions intended to improve patient chronic illness management.⁵–⁷ This management encompasses tasks that persons need to take on so as to live well with chronic condition(s)⁸ such as following a specific diet, daily monitoring for physiologic changes (e.g. blood glucose), and response to those changes.

Lately, reviews have examined mHealth chronic illness self-care interventions’ impact on clinical outcomes,⁶,⁷ whereas previous reviews were limited to reports on mHealth feasibility, acceptance, and usability⁵,⁹ and impact on behavior change⁹,¹⁰ for specific chronic conditions. The two recent articles focused on clinical outcomes are relatively small systematic reviews (in regard to number of studies) of mHealth randomized control trials (RCT) published between 2005 and 2016. Lee et al. included multiple common chronic diseases. Ten of 12 studies reported statistically significant improvement in health and clinical outcomes. Identified mHealth functionality characteristics were data input devices and automated text reminders.⁶ Whitehead et al. focused on apps for four chronic conditions (i.e. diabetes types 1 and 2, cardiovascular diseases, chronic lung diseases). Six of nine studies reported statistically significant improvement in clinical outcomes. Identified mHealth functionality were apps which tended to include data input, data transmission, and sending text messages; and receiving automated text reminders.⁷

However, mHealth interventions targeting self-care of chronic conditions have not had a detailed examination and mapping of the specific mHealth technology features (e.g. data input, messaging) to the health outcomes they target. This mapping would enable investigation of whether specific technology characteristics result in better patient outcomes.

Objectives

This review updates and expands previous reviews to examine mHealth features, viewed through the scope of self-care. Our objective was to: (1) identify empiric (i.e. observational or experimental) mHealth interventions studies explicitly designed for self-care of community-living adults with one or more chronic conditions which assessed the impact on patient outcomes, and among the retained studies (2) categorize and map the study descriptors, mHealth technology features, and study outcomes. We targeted studies sufficiently developed to include clinical outcomes, in contrast to evaluation limited to process outcomes such as feasibility or usability.

Methods

The authors were a health informatician with expertise in home health care and mHealth (PS), a nurse expert in geriatric patient self-care (HB), and a nurse with expertise in chronic conditions and software development for clinician chronic condition management (ES).
Study design

An integrative review methodology was used to synthesize the research results using a narrative analysis\(^\text{11}\) for literature published from 2010 to January 20, 2020. The methodology was to: (1) identify applicable studies; (2) select for review studies that met criteria; (3) organize data from the retained studies; and (4) summarize and report the results. This paper is one of two papers addressing the topic area mHealth in chronic illness management as part of a larger examination of the mHealth human/technology interface. One paper addresses the human aspect or self-care behavior issues in mHealth studies.\(^\text{12}\) This second paper is designed to address (1) the technology aspect or mHealth intervention technology features themselves (i.e. patient or digital device input, general or tailored patient feedback, software features) and (2) their relation to health outcomes and mHealth usage and satisfaction outcomes. Dissemination via this two-pronged approach was designed to support the advancement of the science.

Identify studies

Two authors (PS, ES) developed a search strategy with the assistance of a research librarian (see Acknowledgments). The authors identified a model article,\(^\text{5}\) which was a scoping review of studies focused on the design, development, and evaluation of self-care mHealth for older adults with chronic conditions living at home. From this article the authors gleaned keywords which were used in a PubMed search. This search returned mostly literature reviews, the reference lists of which were hand searched for studies.

Referring to the model article, the authors consulted the research librarian to develop a definitive list of key keywords (i.e. MeSH terms and text words which would also search in the MeSH field) and subject headings in order to capture a comprehensive list of potential sources. They identified and combined keywords to address four research question components: (1) mobile or electronic devices, (2) technology-based health care delivery, (3) chronic condition, and (4) an adult population. The research librarian structured and ran a search query using Boolean operators for each database of peer-reviewed scientific journals searched: PubMed, CINAHL, Web of Science. These databases were available at the librarian’s institution and chosen for their salience to finding mHealth intervention studies. Delimiters in the query were that the articles were published in English, after 2010. Literature reviews related to patient-facing (e.g. for use by patients) mHealth for chronic conditions were also reviewed to retrieve studies to be considered for inclusion.

Selection for review studies that meet criteria

The two authors (PS, ES) established inclusion criteria for article retention: observational or experimental research studies explicitly focused on self-care and with clinical outcomes, which included mHealth technologies designed for use by community-residing adults living with at least one physiological chronic condition. The mHealth technology could be developed by the researchers, and/ or publicly available.

They performed the article selection from each database sequentially, as follows. They independently identified articles for review by searching titles and abstracts and resolving conflicts through consensus. Exclusion criteria were: (1) solely mental health or behavioral health conditions; (2) children (younger than 18 years); (3) study designs which lacked clinical outcomes such as feasibility, pilot studies, protocols, software description; (4) mHealth designed solely for provider use; (5) technologies out of scope: telehealth, social networking, telephonic and telecounseling,
Articles that met inclusion and exclusion criteria through abstract review were independently reviewed in full by two reviewers (PS, ES). The reviewers held regular virtual meetings to discuss their decisions regarding inclusion/exclusion criteria of articles. A result of these meetings was the revision of both inclusion and exclusion criteria as the search progressed so as to better address the research question. The adjustments were to include only physiological conditions (e.g. exclude behavioral conditions), include studies with adults of any age (e.g. not limited to older adults); include studies of mHealth sufficiently developed so as to be studies in an observational or experimental trial with measurable clinical outcomes (e.g. exclude studies limited to user acceptance); and exclude studies which did not electronically generate messages to patients (instead only people such as clinicians or coaches sent messages).

**Organize, summarize, and report the review results**

The reviewers (PS, HB, ES) developed a data charting form, implemented as an Excel spreadsheet, to record selected data from the retained articles. The spreadsheet was revised as the review progressed. The following information from articles identified through the review process described above was entered into the spreadsheet:

- Publication information (Author, title, journal, date)
- Condition(s)
- Sample size
- Study duration
- Research setting country
- Participant age range
- mHealth user interface characteristics (e.g. patient input, electronic device input, personal data used, patient feedback—general or tailored messages)
- Human interaction to augment technology
- Software characteristics: algorithm; gamification
- Outcome type (clinical, satisfaction, etc.)
- Outcome measures
- Main study findings

The two reviewers (PS, ES) abstracted data from the retained articles using this standardized form by charting half the articles and cross-checking the other author’s charted articles. They discussed charting differences until disagreements were resolved. A third author, HB, reviewed the resulting form for completeness and confirmation of technology elements.

The reviewers (PS, ES) synthesized the data using realist synthesis techniques: Analyzing data elements (i.e. technology and patient outcomes) across studies to determine the nature and relationships among and between these data elements to deduce higher order abstractions. This included examining interface characteristics, software characteristics, and human augmentation in light of study outcomes; and investigating patterns across studies. Study outcomes were classified into three types: clinical; performance of care processes (i.e. adherence, health care, or lifestyle changes measures); and usefulness, usage, and satisfaction. Studies were categorized as having positive, mixed, or null (no/null) outcomes based primarily on the reported clinical outcomes. Studies categorized as positive had statistical significance in the primary outcome measure. Studies that did not report clinical outcomes were classified by their reported clinical performance of care processes.
Results

The query used in the three databases, PubMed, CINAHL, and Web of Science, is shown in Figure 1. The search of articles published between 2010 and 2020, which also included those in relevant literature reviews, returned 652 unique studies, of which 32 studies were retained as shown in Figure 2.

Study descriptors

The location of most studies was North America (n=17 studies (53%)) as shown in Table 1. The remaining studies were conducted in Asia (n=6 (19%)), Europe and Scandinavia (n=4 (13%)), Australia (n=3 (9%)), and the Indian sub-continent (n=2 (6%)). The study design of the majority of studies was randomized control trial (n=20 (63%)). However, a few of these studies omitted the power analysis,15–17 or appeared to be under-powered (for all18 or some19 measures) suggesting possible threats to the study findings validity. Additional study designs were single-armed trials (n=9 (28%)), a (3%) three-armed trial,20 a two-armed case-control trial,21 and an observational study.22 A few single-armed trials omitted the power analysis,23 or appeared to be under-powered for all24,25 or some26 measures. The median of the studies’ duration was 19.5 weeks with a range of 427 to 522. The median of the studies’ sample size was 62 participants (range 6 to 710). Two studies focused on multiple chronic conditions,31,32 one of which was in a population over 65 years old.33
The remainder of the studies focused on 1 of 12 conditions, with diabetes (n = 10 studies (31%)) and a group of cardiovascular conditions (n = 8 (25%)) being the most frequent. The median age of the studies’ participants was 52 years of age, with a range of 29 to 72 years of age.

**mHealth characteristics**

mHealth interventions mentioned in the retained studies had characteristics which included the user interface, whether the intervention was stand-alone, software features, and development approach. Two user interface characteristics and whether the mHealth intervention was augmented with human interaction are shown in Table 2.
| Article authors, location | Study design | Sample size | Mean age (standard deviation) | Study duration (weeks) | Condition |
|--------------------------|-------------|-------------|--------------------------------|------------------------|-----------|
| Adams et al.,40 USA      | RCT         | 64          | 35.1 (12.5)                    | 26                     | Hypertension |
| Agarwal et al.,15 Canada | RCT         | 223         | Intervention: 51.5 (10.6)     | 26                     | Diabetes   |
| Arora et al.,46 USA      | RCT         | 128         | 50.7 (10.2)                    | 26                     | Diabetes   |
| Chandler et al.,17 USA   | RCT         | 54          | 46.5 (9.9)                     | 39                     | Hypertension |
| Chhabra et al.,43 India  | RCT         | 93          | 41.2 (14.1)                    | 13                     | Chronic low back pain |
| Chow et al.,30 Australia | RCT         | 710         | 58 (9.2)                       | 26                     | HF         |
| Cook et al.,24 USA       | Pre-post    | 60          | 50.1 (17)                      | 18                     | Asthma     |
| Fukuoka et al.,37 USA    | RCT         | 61          | 55.2 (9.0)                     | 21                     | Obesity    |
| Goh et al.,47 Singapore  | Pre-post    | 84          | 48.2 (8.5)                     | 9                      | Diabetes   |
| Isetta et al.,38 Spain   | Observational | 60       | 56 (10)                        | 6                      | Sleep apnea |
| Kim et al.,19 Korea      | RCT         | 151         | 58.4 (8.9)                     | 26                     | Diabetes   |
| Kirwan et al.,36 Australia | RCT       | 53          | 35.2 (10.43)                   | 26                     | Diabetes   |
| Kleinman et al.,34 India | RCT         | 91          | 48.4 (9.2)                     | 26                     | Diabetes   |
| Lee et al.,6 Korea       | Case-control | 36       | 28.8                           | 6                      | Obesity    |
| Lim et al.,41 Korea      | RCT         | 144         | 60                             | 26                     | Diabetes   |
| Liu et al.,16 Taiwan     | RCT         | 89          | 52                             | 26                     | Asthma     |
| Mallow et al.,31 USA     | Intervention | 30       | 52 (10.0)                      | 13                     | MCC        |
| Martin et al.,28 USA     | RCT         | 48          | 41.4                           | 4                      | Cardiovascular |
| Mira et al.,32 Spain     | RCT         | 99          | 71.9 (7.1)                     | 13                     | MCC, polypharmacy |
| Nundy et al.,27 USA      | Pre-post    | 6           | 50                             | 4                      | HF         |
| Ong et al.,45 Canada     | Pre-post    | 47          | 59.4 (14)                      | 26                     | Kidney disease |
| Plow and Golding,20 USA  | RCT         | 46          | 57.8 (9.48)                    | 7                      | Musculoskeletal or neurological conditions |
| Quinn et al.,29 USA      | RCT         | 163         | 52.8                           | 52                     | Diabetes   |
| Ryan et al.,25 Canada    | Pilot       | 31          | 40.0 (13.9)                    | 21                     | Diabetes   |
| Selter et al.,39 USA     | Intervention single arm | 93       | 46 (16)                        | 13                     | Lower back pain |
| Seto et al.,26 Canada    | Pre-post    | 100         | 53.7 (13.7)                    | 26                     | Heart failure |
| Sieber et al.,22 Germany | Uncontrolled, multicenter, observational RCT | 51 | 54.1 (12.6) | 13 | Diabetes |
| Skrepnik et al.,44 USA   | RCT         | 211         | 62.6 (9.4)                     | 13                     | Osteoarthritis |
| Torbjornsen et al.,42 Norway | RCT   | 151         | 57 (12)                        | 18                     | Diabetes   |
| Toro-Ramos et al.,23 USA | Experimental | 50       | 47.7 (10.3)                    | 26                     | Prehypertension or hypertension |
Table 1. (Continued)

| Article authors, location | Study design | Sample size | Mean age (standard deviation) | Study duration (weeks) | Condition |
|--------------------------|--------------|-------------|-------------------------------|------------------------|-----------|
| Varnfield et al., Australia | RCT          | 120         | 55                           | 30                     | Myocardial |
| Waki et al.,35 Japan      | RCT          | 54          | 57                           | 13                     | Diabetes  |

*Indicates median and/or standard deviation calculated by authors using published study data.

Aspects of the user interface were data input and patient messaging. Data input was characterized as patient input or via a digital device. About 15 studies (47%) described solely patient input, for example: blood glucose readings,22,25,29,34–36 food/caloric intake,15,20–23,25,29,35–38 exercise activity,15,19–23,25,35–39 body weight,23,35,38 and symptom monitoring.16,20,24 One of these studies enabled voice, text, and photo input.35 Five studies17,19,32,40,41 (16%) described only digital input such as wireless transmission of blood pressure,17,31 glycemic level,19,41 weight, activity,19 or heart rate40 readings, or medication administration.32 Nine studies (28%) described both patient and digital input.18,26–28,31,42–45 Examples of digital input included devices,17,19,31,32 and sensors in18,40 or not in cell phones.43,44 Three studies (9%) did not provide a description of the data input.27,30,46

Patient messaging was characterized as a generic message or display, a personalized or tailored message or display, or as unspecified as to either characteristic. About 16 studies (50%) described tailored messages solely. Examples include customized messages based on evidence or clinical targets,15,16,19,21,26,29, and social reinforcement and motivation based on recently input adherence levels,31,40 and personal characteristics related to the condition (e.g. smoking).30 Four studies (13%) described generic messages solely, such as reminders about the intervention.34,38 Five studies described use of both tailored and generic messages.17,24,27,37,39 One study (3%) described tailored and also unspecified messages.44 One study sent tailored emails, not mHealth messages.25 Four studies did not mention messages: Three studies reported displays of user data,20,22,23 one of which also sent tailored messages.32 One study did not describe messages.47

Human interaction that augmented the mHealth intervention was mentioned in seven studies (22%). Clinicians, or trained coaches or mentors provided the interactions which included monitoring,23,29,39 assessment,25 support,23,39,42 counseling,18,23 and responding to patient questions and alerts.18,34,39,42 One study limited coaching to responding to alerts and questions.34

Description of the mHealth software was infrequent and lacked detail. Although most studies generated tailored messages, algorithms (e.g. a rules engine which generated tailored messages based on the patient data) were mentioned or described in nine studies (28%)16,17,19,27,29,30,35,41 including machine learning.43 One study also mentioned gamification (i.e. rewards points).43 One study used natural language processing of patient-entered text.35

Researchers in five studies incorporated publicly available apps.15,20,22,23,36 One app included a commercial curriculum and human coach intervention platform.23

Among studies that mentioned the mHealth development process, most content (logic and messages) was developed by the research team. Two studies described target audience participation.17,32

Study outcomes

Categorization of study outcomes are shown in Table 3. One study47 did not sufficiently describe any of the three outcome types which the study authors ascribed to attrition. Across outcome categories, more than half the studies were RCTs.
| Article authors | Characteristics of the mHealth user interface | Patient feedback (generic, tailored, unspecified) | Stand alone or coach/provider input | Study outcome characterization |
|-----------------|---------------------------------------------|-------------------------------------------------|-------------------------------------|-----------------------------|
| Adams et al.⁴⁰  | None specified                              | Continuous heart rate readings derived from the phone’s video camera via reflective photoplethysmography | Tailored: heart rate; motivational messages | Stand alone | Positive |
| Agarwal et al.¹⁵ | Baseline health, blood glucose, exercise activity, food intake | None specified | Tailored: educational, motivational messages | Stand alone | Null |
| Arora et al.⁴⁶ | None specified                              | None specified                                  | Generic text messages               | Stand alone | Null |
| Chandler et al.¹⁷ | None specified                              | Digital device input (blood pressure, pill dispenser) | Tailored: feedback of BP, heart rate levels; motivational/social reinforcement | Stand alone | Positive |
| Chhabra et al.⁴³ | Surveys                                     | Sensors collected daily activity data            | Tailored: variation in activity level | Stand alone | Mixed |
| Chow et al.³⁰  | None specified                              | None specified                                  | Tailored: support and motivation     | Stand alone | Positive |
| Cook et al.²⁴  | Condition and self-knowledge self assessment | None specified                                  | Generic: input reminders; Tailored: level of control | Stand alone | Positive |
| Fukuoka et al.³⁷ | Weight, activity, caloric intake             | None specified                                  | Generic: input reminders, educational; Tailored: goals | Stand alone | Mixed |
| Goh et al.⁴⁷   | Answers to daily symptom questions          | Daily weight and blood pressure readings and weekly single-lead ECGs | Not described                       | Stand alone | Insufficiently described |
| Isetta et al.³⁸ | Treatment adherence yes/no questions        | None specified                                  | Generic: input reminders; feedback on treatment adherence | Stand alone | Null |
| Kim et al.¹⁹   | None specified                              | Bluetooth glucometer, activity tracker           | Tailored: insulin level              | Stand alone | Mixed |
| Kirwan et al.³⁶ | Blood glucose levels, insulin dosages, other medications, diet, physical activities | None specified                                  | Unspecified tailored weekly message  | Stand alone | Mixed |

(Continued)
| Article authors          | Characteristics of the mHealth user interface                                                                 | Stand alone or coach/provider input | Study outcome characterization |
|-------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------|
|                         | Patient input                                                                                                  | Digital device input (EHR, device)  | Patient feedback (generic, tailored, unspecified) | Coach to respond to patient questions, alerts | Mixed |
| Kleinman et al.          | Blood glucose                                                                                                 | None specified                      | Generic: task reminders; out-of-range follow-up questions | Stand alone | Positive |
| Lee et al.               | Food consumption, activity                                                                                   | None specified                      | Tailored: nutrition/calories; avatar body type          | Stand alone | Positive |
| Lim et al.               | None specified                                                                                                | Automatic upload of blood glucose data | Generic: reminders; Tailored: evaluation messages         | Stand alone | Positive |
| Liu et al.               | Electronic diary: daily asthma symptom score, use of relievers, peak expiratory flow rate (PEFR), and PEFR variability | None specified                      | Tailored: assessment of asthma status, corresponding management advice | Stand alone | Positive |
| Mallow et al.            | Self-monitored readings                                                                                        | Bluetooth scale, glucometer, blood pressure cuff | Tailored: previous readings, reminders for using the self-monitoring devices and taking medications | Stand alone | Mixed |
| Martin et al.            | Activity data                                                                                                | Wearable accelerometer, Bluetooth-enabled with compatible smartphones | Tailored: reinforcement and booster messages based on real-time activity | Stand alone | Positive |
| Mira et al.              | None specified                                                                                                | Automated pillbox                   | Tailored: medication adherence; Unspecified: reminders, medication images | Stand alone | Null |
| Nundy et al.             | None specified                                                                                                | None specified                      | Generic: education; Tailored: reminders                  | Stand alone | Null |
| Ong et al.               | Medication management, symptoms, laboratory test results                                                     | BP                                  | Tailored: condition assessment                            | No coach; clinician monitoring                  | Mixed |

Table 2. (Continued)
| Article authors                  | Characteristics of the mHealth user interface                                                                 | Stand alone or coach/provider input | Study outcome characterization |
|---------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------|
| Plow and Golding                | Physical activity, nutritional behaviors, progress to goals, symptoms                                           | None specified                     | Display                       | Stand alone | Null                      |
| Quinn et al.                    | Blood glucose values, carbohydrate intake, medications, other diabetes management information                  | None specified                     | Tailored: educational, behavioral, and motivational messaging specific to the entered data | Coach       | Mixed                     |
| Ryan et al.                     | Blood glucose, proposed carbohydrate intakes, planned activities                                              | None specified                     | Tailored emails: appropriate insulin doses | Provider    | Positive                   |
| Selter et al.                   | Pain, activity level, medication/coping mechanisms                                                             | None specified                     | Generic: education; Tailored: passive activity-level measurement | Coach       | Null                      |
| Seto et al.                     | Symptoms                                                                                                      | Weight, blood pressure, ECG        | Tailored: message/alert based on the physiological and symptom information | Stand alone | Mixed                     |
| Sieber et al.                   | Daily diabetes routine                                                                                         | None specified                     | Data display                   | Stand alone | Positive                   |
| Skrepnik et al.                 | Pain, mood data                                                                                                | Wearable activity monitor          | Tailored: step count, calories burned, sleep; Unspecified: motivational messages | Stand alone | Positive                   |
| Torbjørnsen et al.              | Blood glucose, food habits, physical activity, personal goals                                                 | Bluetooth glucometer              | Tailored: progress to goal     | Coach       | Null                      |
| Toro-Ramos et al.               | Blood pressure, weight, meals, physical activity                                                              | None specified                     | Dashboard data display         | Coach       | Positive                   |
| Varnfield et al.                | Health diary, blood pressure, weight                                                                            | Activity                           | Generic: motivational and educational materials | Coach       | Positive                   |
| Waki et al.                     | Blood glucose, blood pressure, weight, pedometer counts; voice/text messages about meals and exercise; photos of meals | None specified                     | Tailored: advice on lifestyle modification, matched to the patient’s input about food and exercise | Stand alone | Mixed                     |

Table 2. (Continued)
Table 3. Characterization of retained studies’ outcomes: clinical, performance of care processes, usefulness/usage/satisfaction.

| Article authors   | Clinical outcomes                                                                 | Performance of care processes: adherence/health care/lifestyle | Usefulness/usage/satisfaction of mHealth |
|-------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------|------------------------------------------|
| Adams et al.⁴⁰    | Statistically significant positive difference in clinical outcomes                | Reduced adherence by (higher) intervention dose (length of meditation); mixed adherence results | Usefulness: 94% found the app easy to use, and 96% reported it was easy to learn how to use the app |
| Chandler et al.¹⁷ | Significant decrease in systolic BP at 1, 3, 6, and 9 months; Significant decrease in diastolic BP at 3, 6, and 9 months | Greater increases in medication adherence at 1, 3, 6, and 9 months Good protocol adherence to BP self-monitoring | Satisfaction: 89% of participants reported high satisfaction |
| Chow et al.³⁰     | Intervention group had significant reductions in LDL-C, systolic blood pressure, BMI | Significant increases in physical activity and decrease in smoking | Usage: text messages were useful (91%), easy to understand (97%), and appropriate in frequency (86%) |
| Cook et al.²⁴     | Improvement in Asthma Control Test scores and increased forced expiratory volume | Significant decrease in the number of courses of systemic steroids per patient | Usage: 6 months after the study began, 72% patients continued to use the app Satisfaction: patients found the app easy to use (93%), personalized (79%), and helpful in managing their asthma (74%) |
| Lee et al.⁶       | Significant decreases in fat mass, weight, and BMI                               | Improved adherence to diet                                      | Usefulness: majority of participants found app useful for obtaining information and managing diet process Satisfaction: 58% agreed that the system was easy to use and the contents were interesting |
| Lim et al.⁴¹      | Significant decrease in mean HbA1c levels in both intervention groups compared to control group; more significant decrease in app group; significantly less hypoglycemic episodes in intervention groups | Improved self-management by close and consistent supervision, prompt follow up, recommendations, consistent reminder messages | Satisfaction: 96.1% completed the study: |

(Continued)
Table 3. (Continued)

| Article authors       | Clinical outcomes                                                                 | Performance of care processes: adherence/health care/lifestyle                                                                 | Usefulness/usage/satisfaction of mHealth                                                                 |
|-----------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| **Liu et al.**        | Significant improvements in pulmonary function; improved QoL; fewer exacerbations, less unscheduled visits | Intensive monitoring and management, increase in daily dose of corticosteroids                                                  | Usage: 72% adherent at 6 months                                                                       |
| **Martin et al.**     | Significant increased daily steps (in text receiving group)                         | Not described                                                                                                                 | Satisfaction: high satisfaction with activity tracker and text messages                                |
| **Ryan et al.**       | Significant decrease in HbA1c                                                       | Not described                                                                                                                 | Usefulness: patient found the app simple to use (score of 8/10), and agreed with the bolus calculator suggested dose (8/10) |
| **Sieber et al.**     | Significant decrease in HbA1c                                                       | Not described                                                                                                                 | Satisfaction: 66% still used app after study's end                                                   |
| **Skrepnik et al.**   | Significant reduction in pain during walking                                         | Increased number of steps per day, no difference in PAM score                                                                    | Usefulness: satisfaction: 65.4% of patients and 67.3% of physicians would be likely or very likely to use/recommend device |
| **Toro-Ramos et al.** | Significant improvements in weight, and BP                                           | Increased motivation                                                                                                           | Usage: 80% completed the program                                                                     |
| **Varnfield et al.**  | Significant difference in weight reduction, improved emotional state, and QoL at 6 weeks | No difference in 6-min walk test                                                                                               | Usage: higher uptake (80% vs 62%), adherence (94% vs 68%), and completion (80% vs 47%) rates           |
| **Skrepnik et al.**   | Significant reduction in pain during walking                                         | Increased number of steps per day, no difference in PAM score                                                                    | Satisfaction: >85% of the participants found the step counter to be motivational in reaching CR goals |

Mixed clinical outcomes

| **Chhabra et al.**    | No significant difference in pain; both groups recorded a decline in disability, greater in app group; significant improvement in symptoms and general mobility | Not described                                                                                                                 | Usage: no participants discontinued intervention                                                        |
| **Fukuoka et al.**    | Reduction in BP and weight loss; no significant effect on fasting lipid or glucose levels | Significant, increase in steps per day, reduction in hip circumference, intake of saturated fat and sugar-sweetened beverages in intervention group | Usefulness: usage declined over the 20-week trial but were comparable to or better than rates in similar trials |

(Continued)
| Article authors | Clinical outcomes | Performance of care processes: adherence/health care/lifestyle | Usefulness/usage/satisfaction of mHealth |
|----------------|------------------|---------------------------------------------------------------|------------------------------------------|
| Kim et al.19   | Significant reductions in HbA1c level, percentage of body fat and fasting plasma glucose in intervention group; no difference in severe hypo/hyperglycemic events, blood pressure or lipid profile between groups | No improvement of diabetes self-care activities | Satisfaction: participants were more satisfied with overall health after intervention than at baseline; app was well tolerated |
| Kirwan et al.36 | Significant decrease in HbA1c in the intervention group (no significant change in the control), no significant change in QoL | No significant change over time in self-efficacy, self-care activities | Usage: patients logged 24,720 diabetes parameters in total: 54.0% of the logs related to blood glucose levels, 33.0% to insulin, 12.0% to diet, and 1.0% to exercise |
| Kleinman et al.24 | Greater HbA1c reduction in the intervention versus control group; no difference in blood glucose levels, BP, or BMI | Improved medication adherence, blood glucose testing and communication with doctors | Usefulness: 75% of participants actively used the app at week 24 Satisfaction: high satisfaction on all aspects of the app |
| Mallow et al.31 | Significant decreases in glucose, BP, BMI, no significant reduction in weight | Not described | Not described |
| Ong et al.45    | Significant reduction in home BP readings, no differences in the proportions of patients in the target ranges for potassium, phosphate, or hemoglobin between baseline and exit | Not described | Usefulness: monthly adherence rates over 80%; no drop off of interest over time Satisfaction: all but two participants wished to continue using the app after the study; clinicians expressed satisfaction |
| Quinn et al.29  | Significant declines in HbA1c; differences were not observed for patient-reported diabetes distress, depression, diabetes symptoms, or blood pressure and lipid levels | Not described | Not described |
| Seto et al.26   | Improved QoL in app group; No significant differences in Brain natriuretic peptide (BNP) levels, left ventricular ejection fraction, or hospitalization | Improved post study self-care maintenance and management | Usage: required measurements were completed on average 5–6 days per week; by final week 89% were taking measurements at least three times per week |
Table 3. (Continued)

| Article authors | Clinical outcomes | Performance of care processes: adherence/health care/lifestyle | Usefulness/usage/satisfaction of mHealth |
|----------------|------------------|---------------------------------------------------------------|----------------------------------------|
| Waki et al.35  | Significant decline in HbA1c and fasting blood sugar, no significant difference in BMI, LDL, BP | No change in medication adherence and diabetes self-management | Usage: morning measurements stayed over 70%, but bedtime measurements, except for pedometer count, declined to around 50% | Satisfaction: scores of 70%–100% on the Usability survey |
| No difference/null clinical outcomes | | | | |
| Agarwal et al.15 | No reduction in HbA1c levels | No effect on self-efficacy, QoL, or health care utilization behaviors | Usefulness: overall, low app utilization, with a significant mean decrease over time | Satisfaction: user ratings were completed by about half of participants—53% gave 4/5 stars, 39% gave 3/5 stars |
| Arora et al.46  | Non-significant decrease in HbA1c levels at 6months (except for sub-group of Spanish speakers) | Increase in self-reported medication adherence, ER usage, self-efficacy, performance of self-care tasks | Usefulness: 94% of participants enjoyed the program; the majority believed program was a good way to learn about diabetes, enjoyed the program, and understood all the messages | Satisfaction: very high satisfaction with program; 100% would recommend use to other |
| Isetta et al.38 | Not described | Regular users of APPnea (i.e. for >66% of the study) had significantly higher CPAP usage compared with less regular users (5.6±1.4 vs 4.3±1.3 h/night; p<0.008). Increased participation, improved compliance | Usefulness: 63% of participants used the app for >66% of the study period | Satisfaction: high satisfaction levels for the majority of users |
| Mira et al.32   | No significant difference in HbA1c, BP, and perceived health status | Increased treatment adherence, medication adherence | Usefulness: 59% reported that the app improved medication use, 30% reported partial satisfaction, 12% reported no satisfaction. | Satisfaction: mean score of 80% |

(Continued)
Table 3. (Continued)

| Article authors       | Clinical outcomes                                      | Performance of care processes: adherence/health care/lifestyle | Usefulness/usage/satisfaction of mHealth |
|-----------------------|--------------------------------------------------------|----------------------------------------------------------------|-----------------------------------------|
| Nundy et al.\(^{27}\) | Not described                                          | Significant improvement in self-management in maintenance and improvement in management; no sig change in self-care confidence | Usefulness: although all participants reported comfort in texting prior to enrollment, we observed low participant response rates and requests for additional training in texting. Satisfaction: although most participants reported high levels of satisfaction with the system, a few found the system difficult to use and not helpful in improving self-management. |
| Plow and Golding\(^{20}\) | Non-significant differences between groups in physical function | Improved self-efficacy and self-regulation                      | Usefulness: improvements seen in both app and paper groups compared to control group. Satisfaction: 62% rated overall experience good or excellent. |
| Selter et al.\(^{39}\)  | Not described                                          | Patient engagement                                              | Not described                           |
| Torbjørnsen et al.\(^{42}\) | No difference in HbA1c between groups after 4 months, no changes in QOL | Improvement in self-management in app group and app + counseling group compared to control group; app group exhibited improved skill and technique acquisition | Not described                           |
| Insufficiently described clinical outcomes  | Not described                                          | Not described                                                   | Not described                           |
| Goh et al.\(^{47}\)     | Not described                                          | Not described                                                   | Not described                           |

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About 13 studies (41% of all studies) reported statistically significant positive outcomes, for example in weight,\textsuperscript{18,21,23,30} BP,\textsuperscript{17,30,40} HbA1c,\textsuperscript{22,25,41} LDL,\textsuperscript{30} asthma control,\textsuperscript{24} pain,\textsuperscript{44} and pulmonary function.\textsuperscript{16} Ten studies reported performance of care processes: eight reported improved performance (e.g. Intensive monitoring and management, increase in corticosteroid daily dose\textsuperscript{16}). One study reported no effect on care processes,\textsuperscript{18} and one study reported mixed results.\textsuperscript{40} Of the 12 studies which reported user experience, usage, usefulness, and/or satisfaction was described as high.

Ten studies (31%) reported mixed study outcomes. For example, Fukuoka et al.\textsuperscript{37} reported reduction in BP and weight loss, yet no significant effect on fasting lipid or glucose levels.\textsuperscript{37} Among the six studies that reported performance of care processes, assessments were mixed. Three studies indicated no effect\textsuperscript{19,35,36} (e.g. no significant change over time in self-efficacy, self-care activities\textsuperscript{36}) and three studies reported positive effects\textsuperscript{26,34,37} (e.g. improved medication adherence, blood glucose testing, and communication with doctors\textsuperscript{34}). Seven of the eight studies that reported comparative usefulness/usage/satisfaction reported generally affirmative effects.\textsuperscript{19,25,26,34,35,43,45}

Eight studies (25%) reported null study outcomes.\textsuperscript{15,20,27,32,38,39,42,46} Five studies reported null clinical outcomes.\textsuperscript{15,20,32,42,46} For example, Torbjørnsen et al.\textsuperscript{42} reported no difference in Hba1c between groups after 4 months, and no changes in QOL. Three studies did not report clinical outcomes.\textsuperscript{16,37,39} Six of the eight studies that reported performance of care processes described affirmative effects\textsuperscript{20,27,32,38,42,46} (e.g. increase in self-reported medication adherence and self-efficacy, performance of self-care tasks\textsuperscript{46}). Of the eight studies that reported usage and user satisfaction, two had affirmative effects.\textsuperscript{38,46}

Integration of study descriptors, mHealth technology features by study outcomes

In each study outcome category (positive, mixed, or null), the most often occurring clinical outcomes were blood glucose (14 studies) and blood pressure (11 studies) followed by weight (5 studies) reflecting the large number of diabetes and cardiovascular disease studies. Across outcome categories, studies reported clinical care processes such as performance of care or usefulness/usage/satisfaction as generally affirmative. Careful analysis of study features and the technology by outcome reveals several interesting findings.

Of the 13 studies with positive study outcomes the study descriptor, median study duration, was 21 weeks, slightly above the median for all retained studies (19.5). Study sample size was 60 participants, slightly below the median (62) of retained studies. Median study participant age was 50 years, slightly less than the median for retained studies.\textsuperscript{51} This analysis suggests that slightly longer but smaller sample size studies with more rigorous design in well-studied chronic illnesses in younger patients were more likely to report positive clinical outcomes.

Regarding mHealth technology features, 6 of the 13 studies used digital input: either alone or with patient input (three studies each). About 10 studies used tailored messages. Two studies used display output (and patient input). Of the three studies that used coaching, two included assessment and counseling for weight and blood pressure outcomes. Two studies used publicly available apps. One study described user participation in the mHealth development process. This synthesis suggests that digital input and tailored messages are the more successful user interfaces for supporting chronic illness management sufficiently to change clinical outcomes.

Of the 10 studies with mixed study outcomes, median study duration was 26 weeks, 6.5 weeks longer than the median for all retained studies. Study sample size of 57 participants was less than the median (62) of all studies. Median participant age for the 10 studies was 53 years, slightly above the median of retained studies. Of the studies that reported performance of care, the measure was mixed. This examination indicates studies with a design mostly similar to that of studies with
positive study outcomes, with the exception of having a longer duration, were more likely to report mixed study outcomes.

Concerning mHealth features, nine studies used patient input: either alone (five studies) or with digital input (four studies). Nine studies used tailored messages. No study used display output. Two studies included coaching consisting of monitoring or replying to patients; neither included counseling. One study used a publicly available app. One study mentioned gamification with incentives for outcomes which included pain. The analysis suggests that studies that used patient input and tailored messages were more likely to report mixed clinical outcomes.

Of the eight studies with null reported difference in study outcomes, median study duration of 13 weeks was much shorter than the median duration of all retained studies. Study sample size was 96 participants, much higher than the median (62) of retained studies. Study participant median age was 53.5, slightly above the median age of all retained studies. This exploration suggests studies of shorter duration with larger sample sizes with more rigorous design in a range of chronic illnesses in younger patients were more likely to report null outcomes.

As for mHealth technology, among the six studies which described data input, five used patient input. Five studies used tailored messages and four studies used generic messages (two studies used both). One study used a display output. Two studies included coaching for monitoring and support, and did not include counseling. Three studies used a publicly available app: one study outcome was physical function; another study did not report a clinical outcome. One study described user participation in development. This investigation suggests that studies that used patient input were more likely to report null outcomes.

Discussion

We conducted an integrative review of clinical studies of mHealth self-care applications for patients living with chronic conditions to examine the study descriptors, mHealth technology features, and study outcomes. We identified similarities and variations among the 32 retained studies, and offer suggestions as shown in Table 4. The resulting information enables researchers to identify gaps in knowledge and future avenues of inquiry as shown in Table 5.

Study descriptors and mHealth characteristics similarities

All but one study focused on a single chronic condition in an adult population younger than 65 years. However, multiple chronic conditions is the most common chronic condition internationally. Development and testing of mHealth self-care applications designed for multiple chronic conditions is warranted.

Among the dozen conditions targeted in the retained studies, the most common had quantifiable clinical measures such as blood glucose, blood pressure, weight, food intake, and exercise activity. Notable was an under examination of measures less easily quantified, such as stress reduction, although a few studies assessed symptom monitoring.

Description of mHealth characteristics was variable. Several studies lacked specifics of data input or messages. While most studies sent tailored messages based on data input, only some studies mentioned the software logic to determine which message to send when, and few studies described the logic. We recommend researchers provide a sufficient level of detail of the system description to permit the reader to understand how the system works, as per the STAtement on the Reporting of Evaluation studies in Health Informatics (STARE-HI).
Study descriptors and mHealth characteristics related to study outcomes

Among studies that reported measures, performance of care, and usefulness/usage/satisfaction outcomes were generally affirmative. These outcomes were not indicative of study outcome categorization.

Studies with positive or mixed outcomes tended to have a 20–26 week duration, an approximately 60 participant sample size, and use digital input. Whereas studies with null outcomes tended to have a shorter duration, larger sample size, and rely on patient input.

The study design differences, coupled with the wide range in study duration and sample size, highlight opportunities for future research. Questions include what is a sufficient duration for short-term and long-term clinical outcomes and patient engagement to emerge; and for how long do patients remained engaged in mHealth app use? For example, hemoglobin A1c, weight, and low-density lipoproteins change slowly: Measurement within months will not show large differences. Another question is an appropriate sample size, especially in regards to determining effect size.

Table 4. Study results and related suggestions.

| Study finding                                                                 | Suggestion                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Despite prevalence of multiple chronic conditions, all but one study focused on a single chronic condition | Development and testing of mHealth applications designed for multiple chronic conditions |
| Most studies investigated quantifiable clinical measures of conditions        | Investigation of measures less easily quantified, for example, stress reduction |
| Studies lacked specifics of data input, message content, and tailored message algorithms | Provide system detail as per STAtement on the Reporting of Evaluation studies in Health Informatics (STARE-HI) |
| Differences in mHealth data input characteristics among studies              | In data input design decisions, consider recruitment bias, participation burden, and the digital divide |
| Two studies incorporated target audience participation in development         | In study design decisions, consider participatory development which has the potential to improve intervention effectiveness |

Table 5. Recommendations for future research.

| Recommendation focus | Topic                                                                 |
|----------------------|----------------------------------------------------------------------|
| Study design         | Study duration sufficient for short-term and long-term clinical outcomes and patient engagement to emerge |
| Study design         | How long patients are to remain engaged in mHealth app use            |
| Study design         | Appropriate sample size, for determining effect size                  |
| Study design         | Use of participatory development to elicit and address the target audiences’ needs, using mHealth where applicable |
| Research question    | Impact of digital input on bias related to participant recruitment, burden, adherence, engagement, and retention |
| Research question    | Impact of human interaction on patient engagement and clinical outcomes |
| Research question    | Equipoise for human interaction and high tech                         |
| Research question    | Factors that promote user engagement in serious games                 |
Differences in mHealth data input characteristics among studies point to areas for further research. Dependence on patient input may introduce recruitment bias among older people uncomfortable with the technology. Furthermore, the participation burden of patient data input coupled with the new hurdle of unfamiliar technology use may impact participant adherence, engagement, and retention. Digital input use, such as sensors or voice-activated data input may address these challenges: another avenue of future research. However, use of digital input technologies which require capabilities that may be unavailable to vulnerable populations or people living in under-resourced communities may introduce recruitment bias.

Some studies augmented technology with human interaction such as coaching (“high-touch”). Studies with positive outcomes that included coaching offered counseling, a feature not included in studies with mixed or null study outcomes. Questions of interest are whether high-touch leads to better patient engagement and clinical outcomes; and what is the high-touch/high tech equipoise? Prevalent use of tailored messages and infrequent use of coaching among studies, regardless of clinical outcome categorization, suggests these questions warrant further research.

mHealth development characteristics included build-or-buy approaches and participatory development. While most studies built mHealth interventions, only two incorporated target audience participation in development, with differing study outcomes. Participatory development has the potential to improve intervention effectiveness. Its infrequent use among the studies raises the question whether researchers are implementing in mHealth existing approaches while expecting better outcomes, rather than eliciting and addressing the target audiences’ needs and using mHealth where applicable.

The few studies that used the buy-approach, incorporating commercially available apps, had diverse study outcomes. This finding may suggest a lack of app effectiveness, indicative of the lack of formal assessment, regulatory review, and testing outside of a small, relatively homogeneous population.

An mHealth design feature mentioned in one study with mixed outcomes was gamification, a method that may address the challenge of initiating and maintaining patient engagement. DeSmet et al.’s meta-analysis of serious games for healthy lifestyle promotion found small positive effects on healthy lifestyles, their determinants, and clinical outcomes. However, most games in the meta-analysis were designed for children and young adults, a younger population compared to those living with chronic conditions. Edwards et al.’s systematic review of publicly available games for healthy behavior change found no relation between game content and user ratings. This finding indicates that the question of what promotes user engagement remains unanswered among gaming scientists, and is an opportunity for future research.

**Practical implications**

Those who use or intend to use mHealth self-care applications designed for patients living with multiple chronic conditions should keep in mind that these applications could benefit from further development and testing. Researchers should be aware that these applications often are inadequately described in the studies, that appropriate sample size for effect size estimation remains undetermined, and recruitment bias may not be accounted for in completed studies.

**Limitations**

Characteristic of literature reviews, this review does not claim to be comprehensive nor to fully implement PRISMA guidelines given the more targeted scope of the paper. Instead, it summarizes the research on mHealth for patient chronic illness self-management based on the search terms
used, the databases included, and the review time period. That we used a medical librarian with extensive literature search experience and transparently reported the data acquisition process provides evidence for the dataset’s limitations and scope. Also, we acknowledge that positive results publication bias may have limited the studies available in the databases searched. We did not exclude studies that omitted power analysis or appeared underpowered, nor change authors’ study design classification to reflect sample size. As this was an integrative review, we did not report quality assessment which is required only in systematic reviews and meta-analyses.

Conclusions

We investigated recent chronic condition mHealth interventions experimental studies with a focus on technology features related to clinical outcomes. We offer suggestions about study duration and sample size, and data input and messaging design decisions. We provide these suggestions to advance mHealth science and to future technology developers and researchers for their consideration.

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