

A Meta-Synthesis of Behavioral Outcomes from Telemedicine Clinical Trials for Type 2 Diabetes and the Clinical User-Experience Evaluation (CUE)

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Abstract A worldwide demographic shift is in progress and the aged population proportion is projected to more than double across the next four decades. Our current healthcare models may not be adequate to handle this shift in demography, which may have serious consequences for the ageing population who are more prone to chronic diseases. One proposed remediation is to provide in-home assisted healthcare with technology-intervened approaches. Telemedicine, telehealth, e-health are paradigms found in scientific literature that provide clinical treatment through a technology intervention. In evidence-based medical science, these technology interventions are evaluated through *clinical trials*, which are targeted to measure improvements in medical conditions and the treatment's cost effectiveness. However, effectiveness of a technology also depends on the interaction pattern between the technology and its' users, especially the patients. This paper presents (1) a meta-synthesis of clinical trials for technology-intervened treatments of type 2 diabetes and (2) the *Clinical User-Experience Evaluation* (CUE). CUE is a recommendation for future telemedicine clinical trials that focuses on the patient as the user from *Human-Computer Interaction* (HCI) perspective and was developed as part of this research. The clinical trials reviewed were interpreted from a technology perspective and the non-medical or non-biological improvements of the users (patients) rather than the medical outcome. Results show that technology-intervened treatments provide positive behavior changes among patients

and are potentially highly beneficial for chronic illness management such as type 2 diabetes. The results from the CUE method show how it complements clinical trials to capture patients' interaction with a technology.

Keywords Human computer interaction · Telemedicine · Technology-intervened treatment · Clinical trial · Clinical user-experience evaluation

Introduction

The next four decades will see a demographic shift in the aged population where older generations retire while the proportion of working population comparatively decreases, sometimes termed a demographic time-bomb. Chronic illnesses such as diabetes, heart disease, *Chronic Obtrusive Pulmonary Disease* (COPD), obesity, etc. are more common in the ageing so hospital visits will increase accordingly [1]. This change in demography will negatively impact the patient/doctor, patient/nurse and patient to hospital bed ratios, which will consequently increase the overall costs of healthcare for society, possibly to unsustainable levels [2].

Type 2 diabetes is a chronic disease that continues to grow worldwide, constantly increasing the demand on future healthcare systems. This disease needs close monitoring and long-term management to prevent complications and expensive medical interventions, or even fatality [3]. Intensive management of blood glucose levels has been proven to reduce complications in both type 1 and type 2 diabetes [4]. However, the demographic shift, rising healthcare costs, health complications associated with type 2 diabetes and the cost of treatments raise concern about effective ways to manage the illness.

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Technology-intervened treatments present one possible way to provide care for type 2 diabetes patients. Technology-intervened treatments have been used mostly for chronic illnesses such as cardiopulmonary disease, asthma and heart failure and are now increasingly used for diabetes monitoring [5]. In the medical literature, the technology-intervened treatments are referred as telemedicine, telehealth, telemonitoring, telecare and e-health.

Currently, the benefits of technology-intervened treatments of diabetes, such as telemedicine, are investigated and presented based on the results obtained from clinical trials. The focus of these clinical trials is to compare blood glucose and other medical conditions at the beginning with the results. In the literature, the trials are concluded to be effective based on evidence of the improvement in the medical condition only and not the combination of technology applied in the treatment. Importantly, patients must interact with the technology, which strongly determines the effectiveness of the treatment. However, if there are interaction barriers patients may have with a technology they are not reported, which indicates the results on the degree of effectiveness are incomplete. This information is important for future clinical trials in technology-intervened treatments that should also investigate the Human-Computer Interaction (HCI) between the patient and the technology.

This paper is a meta-synthesis that systematically reviews the use of technology from the patient's perspective with a focus on *Human Computer Interaction* (HCI) and not the medical outcomes. *Meta-synthesis* generally refers to examination and synthesis of findings, across multiple reports to explore new interpretations [6]. Information was collected from a comprehensive list of clinical trials conducted on type 2 diabetes that applied technology-intervened treatments for comparison and analysis. Notably, the focus is on the patient as the user in a HCI environment, where information is gathered about the non-medical conditions of improvement and influence of telemedicine on patient's behavior, rather than medical results. This study examines the results of clinical trials, which are interpreted from a technology perspective and the non-medical or non-biological improvements of the users (NB. the terms "user", "patient" and "participant" are used interchangeably in the context of this paper). The results imply technology-intervened treatments would highly benefit chronic disease management as every trial reviewed recorded significant behavior changes among patients linking persuasive technology and current telemedicine. A *Clinical User-Experience Evaluation* (CUE) was developed based on the results of the meta-synthesis that proposes a recommendation for future investigations and/or clinical trials of technology-intervened treatments.

This paper is organized as follows: section 2 provides background information on the management of type 2 diabetes and the technologies involved in technology-intervened

treatments; section 3 provides the methodology applied in the meta-synthesis of literature; section 4 presents the outcome of the meta-synthesis; section 5 describes the CUE and its use in a clinical trial as a recommendation for future trials; section 6 provides a discussion of findings and section 7 concludes the paper.

Background

The demographic shift

Four challenges may arise from the increase in the ageing population: the demand for healthcare; the retired population versus working population ratio; the patient versus available healthcare ratio; and healthcare costs. The current ageing population in the United States is approximately 8 %, which is expected to rise to 17 % by the year 2050 [7]. In contrast, Australia's aged population will rise from 13 to 25 % by 2056 [8]. The first challenge, the demand on healthcare, will occur because the ageing population is more prone to chronic diseases, which require higher levels of medical care. The second challenge, the retired population/working population ratio, will adversely influence the government's economic and financial plans. The third challenge, the patient/healthcare ratio, is the demographic shift toward an aged population that will negatively influence the patient/doctor, patient/nurse and patient/hospital bed ratios, which will decrease available healthcare. Finally, as the demand increases, healthcare costs will continue to rise and eventually become unfeasible.

Diabetes types and economic cost

Type 2 diabetes is one of the most dangerous chronic diseases that cause serious complications in elderly patients. Although younger populations of first world countries are at risk, the prevalence of type 2 diabetes is now increasing in older populations at alarming rates, which poses a growing threat for the future well-being of the projected aged population.

Healthcare systems have struggled with the overwhelming number of patients suffering from diabetes [9]. Diabetes is one of the most dangerous widespread chronic diseases that create serious complications that can lead to additional disease states. In 2000, medical studies projected the total number of people to suffer from diabetes would rise from 171 million in 2000 to 366 million in 2030 worldwide [10]. However, current figures show this increase reached the earlier predicted figures in only 10 years. In fact, as at 2012, approximately 371 million people worldwide already have diabetes, a total of 4.8 million deaths were due to diabetes and treatment costs were approximately 471 billion dollars [9]. This significant increase is attributed to the demographic shift in the proportion of people over 64 years

of age [11] where 2.5 million of the diabetes related deaths were from the 60 to 79 age group [9].

There are two forms of diabetes: type 1 and type 2. Type 1 diabetes causes the pancreas to cease producing insulin. Without insulin, the body's cells cannot regulate glucose (sugar) uptake into cells and the body burns its own fats as a substitute, which is potentially life threatening if not treated [12]. Patients with type 1 diabetes accumulate dangerous chemical substances in their blood from the burning of fat if not treated with daily injections of insulin. Type 2 diabetes is more common than type 1 and is the most common chronic illness that threatens the well-being of the ageing population. Type 2 diabetes affects 85–90 % of all people with diabetes [12]. While it usually affects older adults, younger people, even children, are now developing type 2 diabetes. The pancreas makes some insulin in type 2 diabetes patients but the body essentially develops immunity to insulin and the amounts produced are not enough to regulate blood glucose. This affliction can initially be managed with healthy eating and regular physical activity but over time, many patients also need medication or insulin injection.

There is currently no cure for type 2 diabetes so the recommended treatment is day to day management [12]. Type 2 diabetes treatments involve diet control, exercise, home blood glucose testing, and in some cases, oral medication with or without insulin. Effective individualized treatments may also incorporate psychosocial, lifestyle and other medical interventions [13]. Diabetes needs strict control of the blood glucose level by balancing within a triangle known as the diabetes triangle (Fig. 1), which consists of food, exercise and insulin (or medication) as the three corners [15]. Patients' decisions sway in this triangle during their daily activities and if there is an imbalance, fluctuations in glucose level occur [14]. These fluctuations in the blood can cause hypoglycemia, a lack of blood sugar, or hyperglycemia, which is an excessive blood sugar ratio. Both hypoglycemia and hyperglycemia are acute conditions because they can cause physical and psychological effects that could range from mild to life threatening.

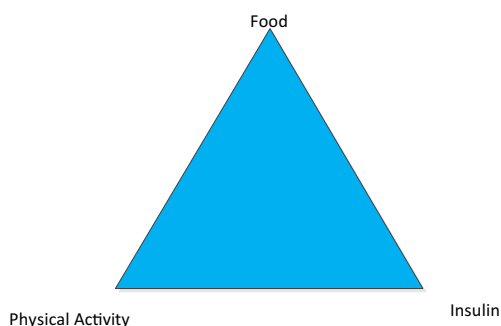


Fig. 1 The diabetes triangle: clinical model of diabetes management. In real this model behaves more plastic and dynamic than the triangle shape envisages [15]

Education, awareness and involvement of patients can help to prevent potential effects [16].

According to Zhang et al. [17], the total annual global health expenditure for diabetes in 2010 was estimated to fall between \$376.0 billion USD and \$672.2 billion USD. This accounted for 12 % of the world's total health expenditure. In 2010, the global average expenditure related to diabetes per capita was \$1330.00 USD [17]. Significantly, the economic cost of diabetes varies in different parts of the world. For example, in Bangladesh, the cost of one diabetic patient for one year is \$28 USD, in China \$193 USD compared to the high costs of \$8,478 USD cost in the United States and Norway \$9,208 USD [9]. Notably, the treatment quality differs vastly depending on the country's healthcare system.

Technology-intervened treatments: Telemedicine, telehealth and e-health

Technologies that are applied in health services and medicine go through a process known as *Health Technology Assessment* (HTA), which consists of:

- The product life cycle;
- The quality standards and regulations;
- *Evidence Based Practice* (EBP);
- Reimbursement processes; and
- Other HTA processes that are regulated by national HTA bodies such as the *Food and Drug Administration* (FDA), USA, the *National Health Service* (NHS), UK, etc.

To provide evidence for EBP, the technologies need to go through rigorous testing methods to prove their efficacy, which is done through clinical trials. Clinical trials are formal procedures that are followed during drug development to check safety and efficacy, which refers to the “capacity of a beneficial effect”, and data for health intervention (drugs, devices etc.). Medical practitioners follow EBPs that aim to find best available evidence from medical science literature before a treatment decision is made by a clinician [18]. EBP supports the clinician in their decision on the risk and beneficial factors of a treatment for a particular patient [19, 20].

“Telemedicine” was introduced in the 1920s [21] but not initially used until the 1970s [22]. Telemedicine is the use of Information and Communications Technology (ICT) to provide clinical treatments over distances [23]. Rapid development in ICT has contributed to the growth in telemedicine initiatives, which continues to evolve. There is now a wide range of communication technologies available for telemedicine [24–26]. For example, after [23] collecting 104 peer reviewed definitions of telemedicine, Sood et al. [23] determined:

“Telemedicine being a subset of telehealth, uses communications networks for delivery of healthcare services and medical education from one geographical location to another, primarily to address challenges like uneven distribution and shortage of infrastructural and human resources.”

“Telehealth” is defined by the *American Telemedicine Association (ATA)* as closely associated with telemedicine but also encompasses a broader range of remote healthcare methods not always involved in clinical services. These technological methods include videoconferencing, still image transmission of, e-health including patient portals, remote monitoring of vital signs, continuing medical education and nursing call centers [27].

The term “e-health” emerged with the growth of the Web and can be viewed as a type of e-commerce [28]. According to Eysenbach [28], e-health was used more by industry and commerce people than academics and was created to be aligned with other “e” words such as e-commerce, e-business, e-solutions etc. His definition is:

“e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology” [28].

Human computer interaction (HCI)

Computer systems are developed through a *User-Centered Design (UCD)* in HCI as opposed to the traditional software engineering and computer science approach where the technologies or functionality are the initial concentration. UCD keeps the human users and their goals central to design and evaluation [29].

Qualitative research methods, which are common practice in HCI, aim to generate richer knowledge about users. According to Boulding (1956), “knowledge does not grow in abstract and knowledge does not exist by itself, it is a property of interaction between agents and the environment and is tied to perspectives, intentions and perceptions”. A message may have a meaning but the meaning depends on the code or set of alternatives from which the message has originated [30]. Qualitative research has been used by Dalcher [31] to understand major ICT and *Information System (IS)* failures in the United States. Dalcher [31] practices qualitative research in software engineering processes and argues that “knowledge

is deeply bound to its original context and thus enables for a contextually correct understanding”. Effective capturing of a precise context is the only way to discover information about the informer’s position, perspective and relationship with the environment. To understand IS failures, Dalcher urges that any useful information must therefore be accompanied by additional contextual information that will shed light on its utility, validity and relevance and any methods adopted need to identify such contextual knowledge [31, 32].

HCI techniques have many methods of evaluation, some are analytical and focus on the system with a set criteria while others are empirical and involve people using the system. Contextual design, interviews, observations, participatory design, ethnography are effective techniques in performing empirical evaluations. HCI mandates anyone who uses a system be classed as a user, so transcending the HCI empirical evaluation methods to technology-intervened treatments, the “user” classification includes doctors, nurses, care providers as well as the patients. This paper focuses predominantly on patients as the most important users because their well-being depends on the proper use of the technology. Patients’ feelings, comfort, partiality, ease of use are very important factors to gauge the success rate of a technology. This paper focuses on the patients’ perspective and the non-medical factors of improvement through telemedicine, telehealth and e-health for the treatment of type 2 diabetes.

Comparison with related works

Ekeland et al. [33] established that besides the traditional questions of clinical benefits and the cost-efficiency of telemedicine, there are “new questions rising in telemedicine”. There are a resurgence of new questions arising in telemedicine such as patients’ perspectives and ongoing collaborative achievements. Ekeland et al. [33] performed a systematic review of other reviews in telemedicine, which provided a strong direction to show the effectiveness of telemedicine for different illnesses in general. Methodologies of the clinical trials of telemedicine are heterogeneous, which makes comparisons of different systematic reviews difficult. However, evidence of an aspect of telemedicine (e.g., effectiveness on patients or cost efficiency) is built through systematic reviews of clinical trials. These reviews support the EBP for medical science.

Verhoeven et al. [34] and Verhoeven et al. [35] presents a diabetes-specific systematic review of telemedicine from technology perspective. Both of Verhoeven et al’s reviews thoroughly explored the technologies for diabetes care in general and concluded that telemedicine is practical, cost-effective and reliable. The authors found that clinical, behavioral and care coordinator outcomes provided a strong basis of data on technology intervened treatments of telemedicine and diabetes.

This paper extends and expands the above works and the approach differs in three ways:

- 1) This paper separates type 2 diabetes technologies from other types of diabetes. Verhoeven et al. [34] and Verhoeven et al. [35] included diabetes types (i.e., type 1, type 2 and gestational diabetes). However, the daily management and effects on the patient differ depending on which type. Gestational diabetes occurs among women during pregnancy and if untreated may cause serious health problems and future diabetes risks to both the mother and child. Type 1 diabetes is fatal; the patient needs to take an insulin dosage to stay alive. Type 1 diabetes is prevalent in the population younger than 40 and often known as “juvenile diabetes”. In contrast, type 2 diabetes is not fatal during the initial stages and with proper management the patient can enjoy a normal and healthy life. Due to the differences in types of diabetes, the technology interventions differ in the urgency and interaction patterns for the varied types of diabetes.
- 2) This paper proposes a method, *Clinical User-Experience Evaluation* (CUE) to capture individual patient perspectives. The CUE aims to expand and explore the findings of Verhoeven et al. [34] and Verhoeven et al. [35] who stated some patients benefited more than others. This paper proposes the method CUE, which will help to further understand these reasons in detail to better inform research in persuasive technology that finds one design does not fit all [36, 37];
- 3) Verhoeven et al. [34] and Verhoeven et al. [35] noted that patients found the technology too complex, costly and time consuming with some patients needed greater assistance with self-care than they received in the intervention settings. In these ICT-based care cases, online training and personal assistance might be necessary and this paper extends from that to provide analysis in two criteria:
 - a. The degree of setup, maintenance and training; and
 - b. Patient withdrawals.

The CUE methodology is aimed to unpack the variations in outcome of individual patients using the technology.

Persuasive technologies and the diabetes triangle

Persuasive technology is a type of technology that is intentionally designed in a way to change a person’s attitude or behavior [38]. Alternately, these technologies are also referred to as *Behavior Change Support Systems* (BCSS) due to the support provided to an individual to make behavioral changes [39]. The use of force (coercion) or misinformation (deception) is outside of the scope of persuasive technology because persuasion is a voluntary change of behavior or

attitude or both. Just-in-time persuasive interfaces can be created to motivate behavior change [40]. Several frameworks exist for designing [41] and evaluating [37, 42] persuasive technology interventions. For example, Intille [43] reviewed that there are four components to effective just-in-time information that include:

- 1) A simple, tailored message that is easy to understand;
- 2) The message occurs at an appropriate time;
- 3) The message is given at an appropriate place; and
- 4) The message uses a non-irritating strategy [44].

Evidence of effectiveness of persuasive technology to control behavior about food and exercise started approximately two decades ago. An example of persuasive technologies for better eating habits is the USA’s Food and Drug Administration (FDA) successful recommendation for eating fruits and vegetables. They promoted better habits via the “5-A-Day Adventures” multimedia application produced on CD-ROM by Dole Food Corp [45]. This “edutainment” application uses animated characters, music, and games to encourage children to eat the number of daily servings of fruits and vegetables. Examples of persuasive technologies for better exercise habits include

- *Nintendo’s* Pocket Pikachu with pedometer is designed to persuade children to do more physical activities consistently [46]. The pet that lives inside the device requires the owner to walk, run, or jump each day to keep the pet alive. This persuasion was very effective due to the popularity the Pokémon animation series and children’s affinity with the characters; and
- Nike’s “Fuelband” is an all-day activity monitor/ pedometer bracelet that tracks total daily steps and reward a person for being active based on a goal known as “NikeFuel” goal.

Research objectives and rationale

Medical science practitioners and healthcare professionals conduct the clinical trials that gather evidence on efficacy and cost-effectiveness of telemedicine interventions. The evidence that is gathered from clinical trials in medical science is through a systematic review for EBP. These systematic reviews aim to ask one (and sometimes more) specific question(s) to gather all supporting evidence from the answer(s).

This paper adopts an approach similar to a systematic review that uses a keyword search to choose papers to review the effectiveness of clinical trials for type 2 diabetes. Evidence in diabetes research shows that intensive treatment with frequent monitoring of the blood glucose helps to reduce further

complications. There are many cases in the literature of clinical trials that examined the use of telemedicine for diabetes treatments to determine the efficacy of such treatments. However, new technologies emerge so rapidly there are many that have not yet been evaluated in clinical trials and without these formal evaluations will never be used in common practice. Because this paper reviews past clinical trials of telemedicine treatments for type 2 diabetes patients, the focus is on the technologies that have been assessed in a clinical trial and not new technologies.

This study is carried out from the perspective HCI because there are significant differences between a drug treatment and a technology treatment, such as telemedicine. The scope of telemedicine technologies is non-pharmacological, non-immunological and non-biological. Instead, the capability of usage is important because results may vary depending on the technological skills of the patients. In many cases, some training is required with technology-intervened treatments to ensure patient's capability and engagement. Contrarily, there are no training required with a drug and their effects are at the pharmacological, immunological and metabolic levels. Because the user has frequent or regular interaction with the technologies, especially in the case of type 2 diabetes interventions, the feelings of these users towards the technologies are almost as important to successful outcomes as the drug treatments.

Research questions

Technology-intervened treatments fall into two domains; the domain of medical science for their utilization in healthcare and the domain of IT for the technology design and user evaluation. The term "user" in telemedicine would refer to doctors, nurses, patients, caregivers who all use the technology and make up the user group. However, only the patients use telemedicine methods as a form of treatment for life altering illnesses, all others use the technologies for the purpose of job requirements. Therefore, throughout the rest of this paper the term "user(s)" are referring to patients. The following two questions were the focus of this review:

1. *How effective have telemedicine services been for the treatment of type 2 diabetes?; and*
2. *What improvements did telemedicine provide for type 2 diabetes patients from technology use perspective?*

Methodology of the meta-synthesis

The methodology of the meta-synthesis involved a systematic review that comprised of four iterative steps (Fig. 2):

Step 1 *Literature search* - Pubmed, Science Direct and Google scholar were the databases used to search for literature on clinical trials of type 2 diabetes telemedicine. No limits were posed on sample population size, intervention type and clinical trial design. The search keywords used were - "type 2 diabetes", "clinical trial", "telemedicine", "ehealth", "telehealth", "telecare", "telemonitoring", "technology".

Step 2 *Intervention types* - All variations of technology intervention for diabetes type 2 treatments were included with no limits on the type of technology.

Step 3 *Content Extraction* - Each paper was analyzed systematically in the following order:

1. Methodology;
2. Conclusion;
3. Discussion; and
4. Results.

The contents extracted from the literature (Table 3) included:

- The type of diabetes (type1 and/or 2);
- The behavioral outcomes;
- The patient dropouts;
- The type of technology used;
- The contents about patients' non-medical conditions;
- The patients' feelings comments about the technology; and
- The patients' difficulty or ease with the technology.

Notably, not all papers contained contents of the above bullet list.

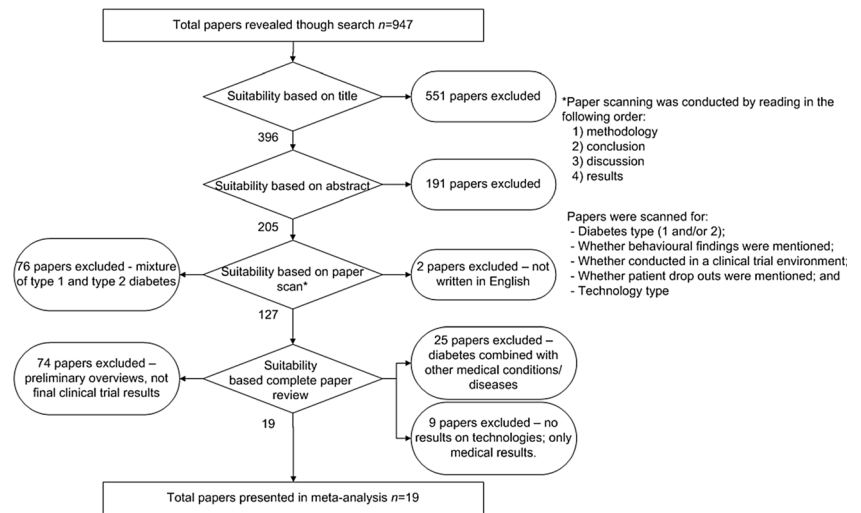
Step 4 *Exclusion criteria* - Because search results most often yielded type 1 diabetes, clinical trial design and clinical trial planning for telemedicine, the following exclusion criteria were used to filter the results (Fig. 2):

Criteria 1) Papers that were about ICT and diabetes-care but were not clinical trials were excluded since this is not a review of the available technology;

Criteria 2) Only papers on type 2 diabetes were included. Papers on telemedicine clinical trials on type 1 diabetes were excluded. However, papers that considered both types 1 and 2 diabetes patients were included but only information on type 2 diabetes were analyzed;

Criteria 3) Papers that only published the plan, proposal or study design of a clinical trial that has not yet commenced were excluded; and

Fig. 2 Methodology of paper selection for the meta-synthesis



Criteria 4) Papers that were published in languages other language than English were also excluded from this review.

A number of prominent diabetes clinical trials were excluded from this meta-synthesis because they did not align with one or more of the criteria (Fig. 2). For example, the vast French IDEATEL diabetes project [47–49] and the telemedicine clinical trial of diabetes conducted by Leichter et al. [50], [51] and Shultz et al. [52] were excluded because they all incorporated both type 1 and type 2 diabetes. Studies by McFarland et al. [53], Stone et al. [54], Estrada et al. [55] and Rodriguez-Idigoras et al. [56] did not report anything about dropout numbers, reasons for dropout and behavioral changes but only presented data of medical conditions improvements. Other exclusions included, for example, Watson et al. [57] who presents a pilot study, Eakin et al. [58] who presents a preliminary trial plan and Davis et al. [59] who presents the technology used at a remote clinic for low-income community. Figure 2 presents the workflow used in the paper selection process and the number of actual papers excluded and included.

The meta-synthesis findings and discussion

Nineteen clinical trials of technology intervened treatments of type 2 diabetes were selected to be included in the meta-synthesis based on the methodology described in section 3.3. Five criteria were used to review the selected trials shown in Table 3, which include:

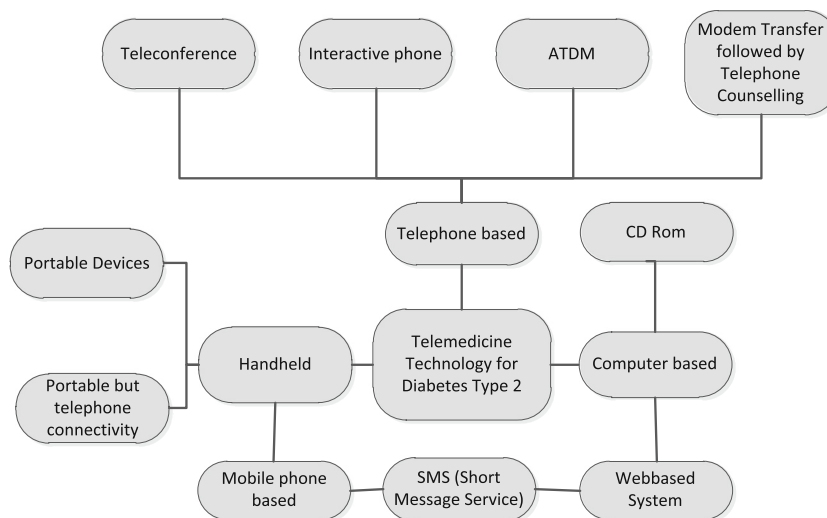
- Criteria 1) The technology type;
- Criteria 2) The degree of setup, maintenance and training;
- Criteria 3) Patient withdrawals;
- Criteria 4) The effectiveness of the telemedicine; and
- Criteria 5) The behavioral improvements.

Technology type

Figure 3 presents a classification diagram of telemedicine technology that has been used in a clinical trial for type 2 diabetes. The technologies range from uncomplicated, where patients and clinicians communicate through phone, email or SMS (short message service), to complex web based frameworks that require connection to the Internet. The different technology categories include:

- Handheld portable devices - devices that are easy for the patient to carry and automatically record time, date and blood glucose levels [60, 61]. For example, sample recommendations such as “Please, decrease the long acting insulin by two units”, “Please add one tablet of sulfonyl-urea in the evening”, “Lack of exercise may be the cause of the aggravated glucose level” and “Your glucose control seems to be good” etc., can be sent using the mobile phone SMS service [62];
- Transfer of data via modem followed by telephone counseling - methods used in earlier periods before the Internet was widely available [63];
- *Automated Telephone Disease Management (ATDM)* – a telephone-based system where patients receive calls at predetermined times and listen to self-management tips navigated via the telephone keypad [64] and the modern version where phone calls are automated to emulate the conversation with a physician [65];
- Glucometer modem transfer followed by graphical report generation [52];
- Data entry of touch tone telephone followed by voice message from clinicians [66];
- Interactive programs on CD Rom to educate on self-management [67];
- Web-based programs on self-management including chat room forums to enlist strangers as supporters [68] the iCare Desktop, the Health Buddy appliance web interfaces

Fig. 3 Classification of the clinical trials of telemedicine for diabetes type 2 based on technology



[69], web-based diabetes management systems [70] and the *Internet Based Glucose Monitoring System* (IBGMS) [71];

- Teleconferencing - a person to person connection via telephone [72]; and
- Pro-active call center treatment support - a telephone-based system where conversation is not automatic like the ATDM. The conversation takes place with trained non-medical operators [73]

Training, setup and maintenance of the clinical trial technologies

To determine the success or failure of technology development, understanding users' needs is important [74]. Bardram [75] stated that "the clinical benefit of a healthcare technology might be diluted significantly if the patients find the technology hard to use". System complexity and poorly crafted interfaces can cause negative emotional responses in the user, which lead to experiences of confusion, frustration, and failure [76]. Further, errors can be frustrating experiences for novice users who are unable to fully understand its cause. In fact, if a user is unable to understand how to appropriately respond to an error, they may perform actions that compound its severity, which invariably compounds feelings of frustration [77, 78].

User training can help to alleviate errors made by users and to help them to understand the system. Ideally, patients should have the knowledge to operate the technology in the appropriate way. However, technology skills vary and patients that fail to use the technology efficiently often experience dissatisfaction, which can ultimately cause the patients to not engage in the treatment and indirectly hamper medical improvements. For this reason, most clinical trials provide a training and instruction manual on how to use the technology. Notably,

the trials reviewed in this paper did not all report the specifics of the technology training applied for the study. Tsang et al. [61] investigated technical issues of patients in their trial. Bujnowska-Fedak et al. [79] found that patients did not find the technology in their trial to be intuitive enough; only 35 % of patients could use the technology alone, 24 % required family support and 41 % were unable to use the system and required constant family assistance. The results found that patients who operated the equipment by themselves benefited more than those that could not or those that required assistance, which shows the importance of investigations of the technology from the HCI (albeit the patients') perspective. Table 3 presents a summary about technology training, setup, maintenance issues of the reviewed trials.

Users often respond to technology as if the device were another person in a social context [80]. An experiment on the "rule of reciprocity" was demonstrated where users were happier to provide helping behavior to a computer that had assisted helped them previously than to a different computer [40]. Further laboratory experiments examined how users are susceptible to flattery from computers and this flattery has the same effects as if given by a human [44].

Important functions in telemedicine are the setup and maintenance of the devices in the users' home because patients should not be expected to have this knowledge. Generally, technical support is usually provided to assist with these functions as well as troubleshooting any technological problems that arise. Problems and negative experiences can alter a user's trust in a technology. These results show that if patients have to troubleshoot the telemedicine technology, the effectiveness of the treatment can decrease indirectly as users (patients) stop using the technology due to frustration. Because the focus was predominantly on the medical data and not the technology used, the majority of clinical trials reviewed, did not report any technical problems or maintenance information. Yet one study by Faridi et al. [81] reported that the technology barrier,

which was the difficulty of using a mobile phone, had caused lack of adherence to a mobile phone based system.

Participant withdrawal and/or dropouts

The reasons for participant withdrawal, shown in Table 3, were not reported in the majority of the nineteen reviewed trials reviewed. There were two withdrawals reported by Rutten et al. [60] due to lack of motivation to adhere to the self-monitoring. The studies by Lavery et al. [82], Cherry et al. [69] and Biermann et al. [63] did not report any dropouts. Izquierdo et al. [72] reported several patients who did not send the data in time so were withdrawn by default. There were a large number of dropouts in the following studies: 10 by Shultz et al. [52], 43 by Glasgow and Toobert [67] and 37 by McKay et al. [68], but the reasons were not reported. Williams et al. [65] found four dropouts from 60 patients, due to patients' inability to use the blood glucose meter and disappointment with the intervention. The study by Meneghini et al. [66], which had 77 withdrawals, was the only one that posed the question for future research to investigate reasons for not using the system in the trial.

The lack of data about withdrawal and/or dropouts led to three assumptions:

- 1) The reasons were not investigated;
- 2) The reasons were investigated but not published; or
- 3) The reasons were out of the scope of the clinical trials.

Based on these assumptions, the authors of the reviewed clinical trials were emailed and responses were received from three. Two authors stated that withdrawal reasons were not recorded. However, one stated although the reasons for withdrawals were not in the research scope, they were discussed and provided information about patient behavior for this analysis.

The study by Young et al. [73] recorded and published the reasons for dropout and withdrawal. There were 83 dropouts in the intervention group with an additional 22 for call center-related reasons. The reasons reported included: eight participants were not able to cope with the calls; four participants were unhappy with the advice given; three due to the travel required; three changed their minds; and two were too busy to use the intervention.

The tendency for participants to withdraw from a trial would be of great interest from the ICT and HCI perspective. Some patients possibly dropout or withdraw (unless for medical reasons) due to the technology involved. The reasons could be found to relate to usage and interaction issues such as difficulty of use, technical problems, the complexity higher than the patients' skill level and/or the patients' confidence level in, and willingness to adopt, a technology. For example, a publication by Steele et al. [83], proposed that patients' willingness to adopt a technology-intervened treatment could

be influenced by independence, perceived improvement in life and ease of use. All participants believed that independence is of paramount importance to them and they would prefer to remain home and use technology rather than being in a nursing home. If benefits of the technology were explained to the participants most of them had shown willingness to adopt the technology even though they had concerns about change of lifestyle due to its use. Participants commented that they would consider using the system if it is deemed useful, reliable and provides benefits to their current lifestyle. Each participant had different levels of skills to use the technology but they stated that the ease of use was one factor of choosing the technology. Participants mentioned that availability of training, the available quality of support for training would let them use the technology if it was not easy to use.

Patients' withdrawal from clinical trials is common in most clinical trials [84]. Jadad [84] presented a scale that independently assesses the quality of methodology of a clinical trial. The Jadad Scale, also known as the Oxford Quality Scoring System, shows the importance of quantifying the number of withdrawals and dropouts in a clinical trial to assess the effectiveness of the employed methodology [85]. Notably, the reasons for patient withdrawals are often not collected or published even though the number of withdrawals affects the outputs and statistics of the clinical trial. This practice is common because the objective of the clinical trials is to find out improvements in particular medical conditions and cost effectiveness of a telemedicine. However, to create sustainable telemedicine practice, data on withdrawals are significantly important in understanding the reasons why patients dropout and especially if caused by the technology.

Effectiveness of telemedicine for type 2 diabetes patients

The clinical trial results were used to assess the effectiveness of telemedicine for type 2 diabetes patients. Most of the reviewed papers are randomized clinical trials where the blood glucose is measured initially as a baseline and then measured after a certain period after the intervention. The baseline and post-intervention results are then compared between control groups.

This review relied solely on the publications about the clinical trials to extract information, regardless of the specific applied design method so only available results and conclusions were assessed about the effectiveness of telemedicine treatment. Surprisingly, the results were mixed where not all trials agreed that telemedicine for type 2 diabetes treatment was effective. Our results are consistent with the results from [33] who conducted a systematic review of reviews on the impacts and costs of telemedicine service. They found that out of eighty heterogeneous reviewed studies only twenty-one stated telemedicine was effective, eighteen stated it was promising and others raised questions for further analysis.

Behavioral improvements

Significantly, our results found that every clinical trial showed noteworthy positive behavioral outcomes of telemedicine. The trials conclude that even though telemedicine does not improve medical conditions for certain, it does invoke positive behavioral change. However, the literature urges for further investigations due to limited evidence. In addition, when authors found behavioral improvements, which were not the main scope of clinical trial, they mentioned those worth investigating in future to determine conclusive results. Some authors also mentioned the study design was limited. Table 1 summarizes the effectiveness in terms of physical and behavioral improvements.

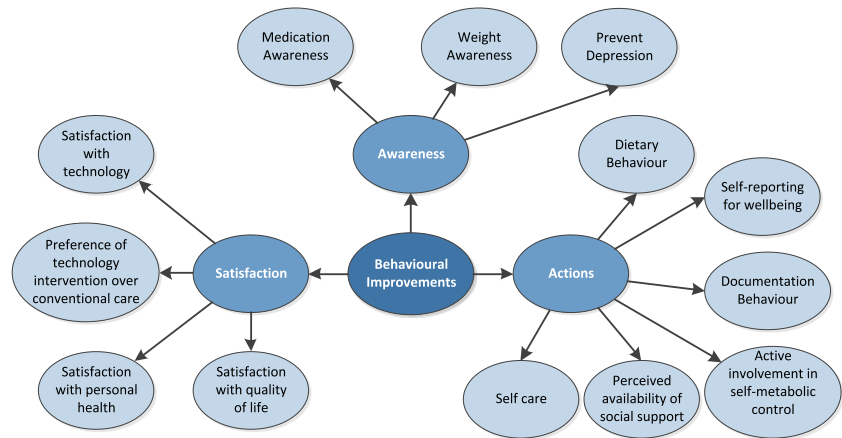
The three specific behavioral outcomes to show improvement (Fig. 4) are classified as actions, changes in awareness about managing type 2 diabetes and satisfaction with the telemedicine healthcare. Actions entail activities that the participant adopts due to the technology intervention. Awareness is the informed state of mind the participant achieves after using the telemedicine intervention. Satisfaction involves the participants' satisfaction from using the technology intervention. The nineteen studies revealed the following findings of behavioral improvements:

- Rutten et al. [60] reported overall improvement in personal health care and quality of life for all patients. The participation stimulated the patients to keep closer control of

Table 1 Effectiveness of clinical trials- physical improvements, behavioral improvements and need for further investigation

Study	Physical Improvement	Behavioral Improvement	Further Investigation Needed?
Rutten et al. 1990	Yes - Weight and/or glucose.	Yes.	No - Concluded to be effective.
Shultz et al. 1991	Yes - Blood glucose level significantly dropped.	Yes - Adherence to dietary guidelines and well-being.	No - Concluded to be very effective.
Meneghini et al. 1998	Yes - Reduced blood glucose and frequency of consults.	Yes.	No - Concluded to be effective.
Piette et al. 2000	Nil improvement in blood. Some improvement in weight.	Yes - Self-management and awareness.	Yes-Effective management and behavior but no results for improved blood glucose.
Glasgow and Toobert, 2000	No.	Yes.	Yes - Effective but further studies for a longer period required.
Biermann et al. 2000	No - Same as normal treatment.	Yes - Satisfied with lifestyle.	No - Concluded to be effective.
Tsang et al. 2001	Yes - Decrease in blood glucose.	Yes - Dietary behavior improvement.	No - Concluded to be effective.
Mckay et al. 2002	No - little improvement in blood glucose.	Yes - Perceived positive personal social support. Dietary behavior improved.	No - Concluded to be effective.
Cherry et al. 2002	Not mentioned.	Yes - Self-management and quality of life improved.	No - Concluded to be effective.
Montori et al. 2002	No.	Yes - Better self-reporting behavior.	Yes - Further studies needed.
Izquierdo et al. 2003	Yes - Blood glucose reduced.	Yes.	No - Concluded to be effective.
Young et al. 2005	Yes- but not the level that authors expected.	Yes - Lifestyle changes and adherence to treatment.	No- Concluded effective for Caucasian but urged further investigations for other ethnic groups.
Cho et al. 2006	Yes - significant improvements.	Yes - Self-management improved - attributed to the recommendations received from medical staff.	No - Concluded to be very effective.
Kim and Kim, 2008	Yes- significant improvements.	Yes - Enthusiasm and motivation in self-management.	No - Concluded to be very effective.
Bujnowska-Fedak et al. 2011	Yes.	Yes - Perceived improvement about blood glucose, diet and diabetes. Improved mental health.	No - Concluded that only patients who are aware of their diabetes gain benefits from the system.
Williams et al. 2012	Yes.	Yes - Improved adherence to self-care and mental health improvement.	No - Concluded to be effective.
Zolfghary et al. 2012	Yes. Significant improvements.	Yes - Patients showed an increase in physical exercise, diabetic medication intake and diet adherence.	No - Concluded to be very effective.
Tang et al. 2013	Yes.	Yes - Continuous engagement was demonstrated.	Yes - further studies needed if nurses can maintain this
Pressman et al. 2014	No.	No.	Yes - additional studies are needed

Fig. 4 Behavioural improvements of telemedicine on diabetes type 2 patients



blood glucose levels and increased their motivation of maintaining good levels;

- Shultz et al. [52] showed that using telemedicine helped patients adhere to a dietary plan and other healthy habits;
- Meneghini et al. [66] found patients became an active participant and got involved in metabolic control. Technology-intervened systems empowered case managers to increase intervention and improve metabolic control. In addition, Meneghini et al. [66] have urged the importance of the psychological foundation, possible system dependencies, and personality traits are contributing factors in the various behaviors that require further study;
- Piette et al. [64] stated the automated telephone assessment resulted in improved self-care, weight monitoring for patients even though the interaction with the nurse was less than six minutes per month. It also allowed patients with behavior reinforcement;
- Glasgow and Toobert [67] found improvements in dietary behavior of the patients. This clinical trial is first of its kind to consider social cognitive-environmental model in an intervention;
- Biermann et al. [63] observed that patients were enthusiastic about sending data and preferred telemanagement rather than daily logging with pen and book;
- Montori et al. [70] work also showed similarly a better way of self-reporting and documenting to improve well-being;
- Izquierdo et al. [72] measured stress levels of diabetes patients through teleconferencing. They found patients' quality of life improved by reducing the diabetes related stress, which helped the patients better manage the illness;
- Cherry et al. [69] showed that overall quality of life was improved, which is evidenced by the SF-12 survey, which indicated a change of self-management behavior;
- McKay et al. [68] showed social support is also important for self-management and awareness, where improvements in patients' perceived availability of social support was

relative to participants who only had computer access to information about diabetes. Connecting with other type 2 diabetes patients helped patients to engage better in self-management;

- Tsang et al. [61] reported that dietary awareness was generated after use of the technology;
- Young et al. [73] published the behavioral outcomes in a companion article and reported participants receiving the intervention continued to report high levels of satisfaction with their treatment after a year and more than 90 % strongly agreed or agreed that the telecarer approach was acceptable. Qualitative comments pointed to the importance of a personalized service; increased feelings of well-being, including confidence and self-control; help with problem-solving; and patients developing rapport and a strong bond with the telecarers [86].
- Cho et al. [71] expected a majority of patients' questions to be about drug dosage during the 30 month trial. However, they concluded that the contrary was true because only 20 % times patients actually sought for glucose dose adjustment of the drug. Instead, the authors found 41 % of the recommendations made were for patients seeking encouragement and problem assessment and 30 % of patients asked for some sort of counseling.
- Kim, Kim [62] attributed the significant physical improvement of patients was due to their behavioral changes. Patients were found to have more contact with caregivers through SMS and internet based messages, which improved their enthusiasm, motivation and engagement in blood glucose monitoring.
- Bujnowska-Fedak et al. [79] found that patients who used the system alone benefited with an increased quality of life score shown in the surveys that indicates better mental health and higher prevention against depression.
- Zolfaghari et al. [87] found that both SMS and telephone intervention found significant improvements in behavior.
- Tang et al.[88] found physical improvements through behavior change and attributed it to the Hawthorne effect,

where patients are influenced by awareness of being observed. The authors intended to understand factors that might predict patient engagement.

The findings on behavioral improvements in this meta-synthesis show positive results in type 2 diabetes treatments and comply with the diabetes treatment based on diabetes triangle in Fig. 1. The compliance is only towards two corners of food and insulin since the technology interventions did not have physical activity monitoring functions. Yet there were awareness of weight management. Improvements in dietary behavior and medicine are positive indicators that these telemedicine technologies are moving towards patient improvement. Furthermore, the satisfaction with the technology by patients in the trial shows promises for these kinds of interventions. The behavioral outcomes are positive although the medical outcomes in terms of blood glucose are not always positive.

Recommendation for future clinical trials

A lack of data exists on user (patient) experience with technology-intervened treatments in clinical trials of type 2 diabetes, as discussed in section 4. In-home telemedicine technologies will not serve their purpose if they are not adopted by the users. Information can be collected via the users' experience and interaction to find out reasons that influence effectiveness of telemedicine technologies. Bardram [75] claimed the results of failure to use a technology can be diluted in the end results of a clinical trial. Early evaluations during clinical trials can help technology and medical researchers learn more about user experience to identify the positive and negative user interactions. To remediate this situation this paper proposes the *Clinical User-Experience Evaluation (CUE)* method to complement clinical trials in EBP. The name CUE was inspired by Bardram's [75] *Clinical Proof-of-Concept (CPOC)*, which is a prototype evaluation phase with a few patients prior to a full-scale clinical trial.

The clinical user-experience evaluation (CUE) project

The CUE was conducted in conjunction with a clinical trial of a telemedicine in-home monitoring device for type 2 diabetes administered by the *Townsville-Mackay Medicare Locals (TMML)* in North Queensland, Australia. The TMML trial used a randomised controlled method to explore whether remote access to clinical care, supported by telehealth technologies over high speed broadband, leads to improved diabetes control [89]. Patients were randomly selected to assign participants to an intervention group and

to a control group. The intervention group received additional diabetes care from a care coordinator nurse via an in-home broadband communication device that comprises of a tablet computer, an automatic glucometer, which is a blood glucose measuring device, and an automatic sphygmomanometer, which is a blood pressure measuring device. The device captures clinical measures, provides regular health assessments and videoconference with other health professionals when required [89].

To distinguish the CUE from the TMML randomized clinical trial, the CUE methodology was developed as a three stage process:

1. *A contextual inquiry* that is performed in-situ in a patient's home. During this stage the patient uses the device while using the "think-aloud" method as the observer takes notes. Then, the observer interviews the patient regarding the process of using the device. The questions are based on the actions that were observed while the patient was using the device. This process is conducted during a patient's regularly scheduled time for using the device.
2. *A semi-structured qualitative inquiry (interview)* to understand patients' experience and expectations. The questions are predominantly developed during stage one. The interview takes place directly after stage one, while perceptions are still fresh in the mind of the user. The questions are structured around the patient's perceived benefits of the device, the patient's choice of locations, their expectations of the device, their impressions about the design of the current device and the patients' thoughts of how the device should be.
3. *An anonymous survey* to encourage free expression without reservations. During the first two stages, the CUE allows for observation of certain behaviour of the participants in person. To verify these observations, an anonymous survey is conducted in the third stage to obtain patients' feedback and opinions on the observations from the previous stages. This survey was administered 8 months after stage two to allow for reflection and was anonymous to uncover thoughts that may not have emerged in the in-person interviews.

Implementation of CUE

The CUE does not interfere nor impede in the traditional clinical trials but is an additional activity that is carried out concurrently by non-medical staff. Table 2 describes alignment of activities of the clinical user evaluation to the activities of the full medical clinical trial.

Participation in the CUE was voluntary and nine patients were selected based on a subset of intervention

Table 2 Interweaving the CUE within the overarching clinical trial

Activity/Detail	Clinical User-Experience Evaluation	Clinical Trial
Investigation aims	Investigates patients' perception, understanding, feeling and usage of a technology for healthcare.	Investigates patients' medical condition with an intervention that can be a drug or a technology.
Outcome	To provide user feedback about using the trial technologies and a guide for future improvement of the technology including features that were lacking or non-existent that would benefit the treatment process.	To provide enough evidence for medical practitioners to make sound judgments.
Sample size	A smaller sample population similar to HCI qualitative user evaluation is appropriate [101].	Requires large sample population to provide substantial and robust evidence.
Time period	Conducted at least after 3 months from the start of the clinical trial. Each participant was contacted twice.	Conducted over an extended period of time depending on the treatment with data collected regularly.
Regulations	There are no HTA regulation limitations. CUE is a form of observational interview that tests interaction with a device without interfering in any medical protocols, there is no physical or psychological stress. CUE is conducted at the regular times a patient uses the technology as part of the overarching clinical trial.	Rigorous form of testing that must follow HTA guidelines. Clinical trials often include psycho-social analysis questionnaire.
Investigator	Can be carried out by anyone working in the field of HCI with simple practice and observational skills.	Carried out by medical staff, or caregivers who have either medical credentials or training in healthcare and/or social work.
Recruitment	Participants come from the clinical trial intervention group.	Larger samples of volunteers are sought who have specific medical conditions.
Ethics	Privacy of information is required and participant must provide written consent.	Strong regulated ethical process and abiding by HTA regulations.

group within the TMML clinical trial. The CUE contextual inquiry (stage one) and the qualitative inquiry (stage two) were completed after a 3 months period from when the patient was given the initial training by the nurses on how to use the in-home monitoring device. This time period allowed the patients to become accustomed to the device to ensure the data from the CUE was not influenced by the initial novelty or unfamiliarity with the device [90, 91]. Two of the nurses who went to the patients' homes during setup of the technology, training with the technology and provided support through telephone communication with these patients were also interviewed.

Data analysis of the CUE

All contextual inquiry and qualitative inquiry sessions were audio-recorded, then transcribed. Photographs and field notes were taken at the time of the sessions. The contextual inquiry was analyzed to recommend patient-centered system design by following steps from contextual design [92]. The qualitative inquiry transcripts were open-coded and themes were developed from patients' answers. NVivo software was used to manage the codes and themes. During the contextual inquiry patients were observed while they uploaded their blood glucose and blood pressure. The patients led each session and talked about the device like an instructor while the researcher listened and took notes.

Preliminary results from the CUE

Results from CUE provided deep insights into how patients perceive the device and how to improve the device.

Types of users (patients)

All patients do not interact with the device the same way. Individual variations of their interaction were noted through CUE. The patients could be grouped as the following:

- *Proactive patients* are very proactive and used the technology to upload their regular blood glucose and blood pressure regularly. In addition, the proactive patients also used diabetes awareness information that was available on the tablet PC.
- *Accepting patients* welcome the use of the technology but did not spend extra time to explore the features for diabetes awareness.
- *Indifferent patients* use the technology because they are told they have to. They do not resist and do not seem to care either way.
- *Resistant patients* are opposed to using any technology. For example, one patient was resistant due to their lack of experience in technology use and lack of ownership of a computer or mobile-phone. This patient was in the clinical trial intervention group due to the random participation for recruitment (i.e., a lottery

method). Notably, although resistant, the patient used the technology because they felt they had to commit to the clinical trial.

Ease of use

All patients were given training to use the technology by their nurse. A nurse went to a patient's home during set up and trained the patients for approximately one hour. The training consisted of demonstration by the nurse followed by practice sessions in the presence of the nurse. Two nurses were also available during the rest of the clinical trial to answer questions about problems with the technology. In cases when the guidance through phone was unable to resolve the problems, the nurse would visit a patient's home personally or send a technician.

Two patients were not as comfortable with the technology as the others despite having used the devices for more than 13 weeks before participation in the CUE. One was a patient from technology "resistant" group while the other was from the "indifferent" group. The user types of section 5.2.1 could be related to a patient's ease of use with the technology. According to the nurses, "What patients describe as a problem with the technology is often not what the real problem is". The nurses went on to state that "often it is a step that the patients forgot but they thought the technology had problems".

Other significant results

The implementation of the CUE during this clinical trial revealed further rich information including:

- Patients' perceived benefits;
- Patients' future decision to use the technology;
- Patients' feedback about the technology [93]; and
- Recommendations of the technology design

These results are very detailed and would be reported in future publications.

Discussion

Although numerous clinical trials have been conducted that examine the effectiveness of technology-intervened treatments, the results and conclusions are not absolute. The business and technology communities continue research and development of these treatments. TechCast [94] performed a study to determine the future of medicine to be telemedicine, telehealth and e-health services. This study found the global telemedicine market grew from \$9.8 billion USD in 2010 to \$11.6 billion USD in 2011 and was expected to reach \$27.3

billion USD in 2016, which is an additional 15 % global rise in adoption. Conversely, technology-intervened treatments expect patients to have a more proactive role in comparison to the traditional healthcare methods [95]. Even if patients are provided with the latest state-of-the-art technology at home, the technology-interventions will not benefit the future healthcare systems if they do not use them. For this reason, research into the technology interventions through a HCI perspective is important.

Benefits of telemedicine could be lost due to the problems faced in the use of the technologies. A clinical trial study by Bujnowska-Fedak et al. [79] reported that patients who operated the device by themselves gained greater benefits of the medical treatments than those that could not or would not use the technology. The study reported only 35 % of patients could use the technology without assistance and they gained more benefits from the technology-intervened treatment.

The importance of user-experience of patients is valuable in a clinical trial. A study by Cho et al. [71] reported that during telecare support, the researchers expected a majority of patients' questions to be about drug dosage. Unexpectedly, the study discovered approximately 80 % of patients sought encouragement and counseling while only 20 % of patients sought information on drug dose adjustment. This discovery showed the potential telemedicine could have towards patients' well-being through the information dissemination, support and influence.

Generally, user-centric design for assistive health technologies is carried out on users who are not patients due to ethical reasons or strong regulations by HTA. The inclusion of CUE as a part of an overarching clinical trial with real patients in real situations can be beneficial to the design process of these technologies because it explores and extracts knowledge on patient perceptions of the technology.

Promise of persuasive technology in telemedicine for type 2 diabetes treatment

Persuasive technology intervention in telemedicine is beneficial for diseases like type 2 diabetes where the only cure is through behavioral management [96]. Diabetes needs strict control of the blood glucose level by balancing food, exercise and insulin (or medication) within the diabetes triangle (Fig. 1) [13]. To educate and motivate a change in eating behavior the persuasive techniques would be an initial recommendation to inform diabetes patients of good food and food to avoid. There exists already multimedia applications via CD-ROM for diabetes self-management counseling that are educational and showed behavior improvements [97]. These applications were simply educational; they could potentially be even more effective by employing persuasive technologies. Motivation and awareness to build better habits for exercise and medication could also be accomplished through

persuasion. For example, just-in time messages or triggers can be setup with the appropriate device reminders to take insulin injection or medication.

Persuasive in-home monitoring can make the management of blood glucose levels timely and provide an efficient day-to-day management of diabetes to prevent complicated stages. Interventions for behavior change has been identified as a major cornerstone for changing dietary behaviors [98]. A US study of over 17,000 patients enrolled in a home telehealth program reported a 20 % reduction in hospital admissions and 25 % reduction in bed days of care for chronic health condition management [99]. Recent work has conceptually explored the promises of persuasion techniques if added in existing telemedicine type 2 diabetes in-home monitoring interventions [96].

Pervasive technology and telemedicine

The advent of pervasive technologies (mobile devices, wireless sensor networks) provides a great future for telemedicine in general and specifically for chronic diseases like type 2 diabetes. Telemedicine through the use of pervasive technologies have the potential to change the paradigm of current healthcare models [95, 100].

Two potential challenges may arise. First, a new technology must show enough clinical evidence of improvement of health conditions compared to alternative therapies that have existed before, which is challenging and may slow down the use of pervasive technologies in telemedicine and healthcare. Bardram and Mihailidis [100] called this phenomenon the antithesis of the technology-push mindset found in consumer technologies. Second, how welcoming/resisting will the doctors and nurses be to the new technologies that require changes in the existing healthcare services?

Conclusion

This paper is a meta-synthesis that systematically reviewed a comprehensive list of clinical trials of technology-intervened treatments for the care of type 2 diabetes from HCI perspective. This paper identifies patients as the most important focus of technology-intervened treatments. The meta-synthesis determined there is a need for a new method that could capture the experience of users (patients) in a clinical trial of technology-intervened treatments for type 2 diabetes. To satisfy this need, this paper describes the CUE, which was developed to complement clinical trials in EBP. The CUE was implemented concurrently in a clinical trial and provided insights about the patients as technology users.

The objective of this paper was to assess the types of technology applied and their effectiveness in technology-

intervened treatments, which led to two important conclusions to inform future exploration of telemedicine and persuasive technology. First, the reasons for dropout or withdrawal of patients can significantly inform the future development and design of information technology used in technology-intervened treatments. Improvements in telemedicine require knowledge and understanding of how users (patients) physically and emotionally act and react with the technologies. However, currently, the reasons for withdrawal have not been investigated in clinical trials. Second, all of the reviewed papers reported patients had significant behavioral changes via telemedicine techniques although improvements in the physical conditions were not consistent. The outcomes show the potential of telemedicine in the treatment of diseases like type 2 diabetes where the key to success is behavioral change and continuous management.

This paper showed that telemedicine have been effective in providing the education and awareness in the patients' own well-being. The key to surviving diabetes involves a long-term management of the diabetes triangle model, which includes a balanced control of diet and exercise, home blood glucose testing and insulin (or medication) if required. The majority of the studies reviewed concluded that telemedicine provided significant health improvements in weight management and blood glucose levels.

In-home technology intervened healthcare such as telemedicine and other pervasive healthcare technologies will increase with the demographic shift. Currently, there is a disjuncture between telemedicine and persuasive technology for type 2 diabetes. The technologies used in the clinical trials this paper investigated did not have a persuasive design consideration, yet they had positive behavioral changes to affect well-being. Recent studies suggest that persuasive technology could change behavior in patients with in-home technology intervened treatments. The combination of telemedicine and persuasive technology can provide better solutions for type 2 diabetes treatments.

The full results of CUE project with in-depth analysis will be published in future work. Both the technological and medical reasons for patient withdrawal from clinical trials is important to understand. During future trials, researchers are urged to take an approach towards data collection that would include patients' physical and emotional actions/reactions with the technologies. Future work will conduct further investigations of measuring effectiveness and integration of telemedicine technology.

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Appendix I

Table 3 Summarized results of reviewed clinical trials classified by technology type, training or setup issues, participants and dropouts

Study/Location	Participants	Type of technology	Training/Setup/ Maintenance	Reasons for withdrawals
Rutten et al. 1990 - Netherlands	149 of 171 eligible type 2 diabetic patients, 40 to 75 years	Handheld portable self-monitored devices	Not mentioned	2 withdrawals due to motivation
Shultz et al. 1991 - Vermont USA	30 Diabetes Mellitus patients specific types not specified.	Glucometer connected to a modem at home. Data transfer to medical center for graphical representation to reported back to patient	Patients were given verbal instructions. No technical difficulties.	10 withdrawals, XX due to unrelated medical conditions and the for the remaining the reasons were not reported
Meneghini et al. 1998 - Florida USA	187 type 1 and type 2 diabetes.	Patients entered diabetes data on a touch-tone telephone. Voice messages on progress were then left for patients.	Patients received a 15 min induction and user manual. No technical difficulties.	77 withdrawals- authors propose to question the reason in future
Piette et al. 2000 - California USA	280 type 2 diabetes.	ATDM (Automated telephone disease management)	Not mentioned	5 refused follow up. 8 refused data collection- reasons not reported
Glasgow and Toobert, 2000 - Oregon USA	320 of 419 eligible type 2 diabetes (76 % enrollment).	Interactive CD ROM program with touch screen capability so o the patient could receive immediate personalized data	Not mentioned	43 withdrawals - reason not reported
Biermann et al. 2000 - Germany	46 type 1 and type 2 diabetes.	Telephone advice given by clinician in response to transmitted blood glucose	Training via a diabetes education program.	No dropouts reported
Tsang et al. 2001 - China	20 initial patients.	Handheld electronic diary connected to the telephone line	Two weeks training prior to the trial. No technical difficulties.	1 withdrawals- reason not reported
Mackay et al. 2002 - Oregon USA	160 of 265 eligible type 2 diabetes (61 % enrollment)	Internet based self-management	Not mentioned	37 withdrawals- reason not reported
Cherry et al. 2002 - Texas USA	169 type 1 and type 2 all were novice computer users	Telemedicine Diabetes Disease Management - A web based interface for patient input.	Not mentioned	Withdrawals not reported
Montori et al. 2002 - Minnesota USA	200	Implemented DEMS		
Izquierdo et al. 2003 - New York USA	56 type 2	Personalized teleconferencing to educate patients		1 due to failing consequent appointments. 8 due to lack of time
Young et al. 2005 - Salford, UK	591 type 2	Pro-Active Call Center Treatment Support (PACCTS), using trained nonmedical telephonists supported by specially designed software and a diabetes nurse	Not mentioned	83 dropouts with an additional 22 (5.6 %) dropped out for call center related reasons (e.g., not being able to cope with the number of calls). Other dropout reasons included: 4 not happy with the advice given, 3 changed their minds, 3 due to travelling and 2 were too busy.

Table 3 (continued)

Study/Location	Participants	Type of technology	Training/Setup/ Maintenance	Reasons for withdrawals
Cho et al. 2006 - South Korea	40 type 2	Web site (www.biodang.com) to upload blood glucose and interact with doctors and nurses	Yes	Not reported
Kim and Kim, 2008 - Seoul, South Korea	18 type 2	Continuous education and reinforcement of diet, exercise, medication adjustment with frequent self-monitoring of blood glucose levels through SMS on mobile phone and internet	Yes	Not reported
Bujnowska-Fedak et al. 2011 - Poland	50 type 2	In home wireless glucose monitor and transmitter and transfer through internet	Yes	3 dropouts 2 for being disinterested with the technology
Williams et al. 2012 - Brisbane, Australia	60 type 2	Automated and interactive telephone system that emulates physicians.	Not mentioned	4 dropouts Unable to use the blood glucose meter and disappointed with the technology
[86]- Iran	39 SMS type 2, 41 telephone type 2	SMS and telephone conversation in two separate interventions.	Yes	3 dropouts
[87]-Several states, USA	405 type 2	Palo Alto Medical Center's own online diabetic management system that comprises of five components of web-based, infrared, reports, teleconsulting, video instructions	Yes	54 dropouts- reasons not reported
Pressman et al. [102]-California, USA	118 type 2	Telemonitoring Diary provided by Samsung	Yes	9 % of the 118 paties dropped out- reasons not reported

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