

## Clinical Trials on Computer Based Telemedicine: A Systematic Review

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### Abstract

#### *Introduction*

Recent developments in the field of ICT may have an impact on telemedicine. This systematic review aims to evaluate the recent clinical trials of telemedicine in relation to store-and-forward, real time and remote monitoring methods.

#### *Method*

Articles were obtained from November 2007 to November 2009 using the MEDLINE database. Studies reported on clinical trials were included and those indicating the use of telephony, electrical equipment and feasibility studies were excluded. Articles were abstracted and grouped for various disciplines for analysis.

#### *Results*

There were three large sample Randomised Control Trials (RCTs), nine small sample RCTs, four prospective studies, three retrospective studies, one cohort study, four case control studies, and fifteen descriptive studies. The three large sample RCTs have been reported one each in neurology, diabetes and dermatology.

Thirty nine articles selected were nine on neurology, four each on psychiatry, diabetes and cardiology, three each on ophthalmology and dermatology, two each on acute care, transplant and ENT and one each on child abuse, endoscopy, general practice, leprosy, nephrology and radiology.

After further exclusion, rest of the 27 articles revealed that the outcome had improved in 41%, comparable in 15%, benefited in 33% and not enhanced in 11% when telemedicine was compared to conventional approaches.

#### *Conclusions*

Most of studies reported have revealed advantages of telemedicine against conventional methods of care. However further large sample randomized controlled trials are necessary to confirm these results.

Keywords: Telemedicine, Clinical Trials

### Introduction

Telemedicine is the use of information and communication technology to provide health care services to individuals who are at some distance from a selected health care provider<sup>(1)</sup>.

There are three major types of computer based telemedicine applications in terms of how the information is transferred:

- a. Store-and-forward method in which recorded data is transferred offline
- b. Real time method which involves online two way interactive videoconferencing
- c. Remote monitoring method in which patients are monitored at a distance which can either be hospital or home based.

Telemedicine techniques have been adopted for various disciplines such as radiology, dermatology, cardiology, pathology, surgery, psychiatry, neurology, ophthalmology and

pharmacy<sup>(2)</sup>.

Over the last few years, many aspects of information and communication technology seem to have changed worldwide and that is likely to have made an impact on telemedicine activities. Evidence on the effectiveness of telemedicine when compared to face-to-face care is sparse<sup>(3)</sup>. Previous reviews on telemedicine have studied assessment methods, cost effectiveness and patient outcomes. In this paper an attempt has been made to review the clinical trials that used telemedicine interventions reported in the scientific literature during the last two years. This study would help to identify the key areas in which computer based telemedicine have been applied successfully recently.

## **Methods**

Computerized literature searches were performed using the MEDLINE database for articles from November 2007 to November 2009. Inclusion criteria were the key words telemedicine, human, and clinical trial.

Exclusion criteria were the use of telephony, electrical equipment and feasibility studies. Each title and abstract was retrieved and reviewed. Full text articles also were studied where possible. Articles were classified according to the system by Jovell and Navarro-Rubio<sup>(1,4)</sup> (Table 1), where 9 levels are described in descending order of strength. Articles were then grouped into subsets according to the disciplines and analyzed for their content.

**Table 1.** Classification of studies (According to Jovell and Navarro-Rubio)

1. Meta analysis of randomized controlled trials (RCT)
2. Large sample randomized controlled trials
3. Small sample randomized controlled trials
4. Nonrandomized controlled prospective studies
5. Nonrandomized controlled retrospective studies
6. Cohort studies
7. Case-control studies
8. Non-controlled clinical series, descriptive studies, consensus methods
9. Anecdotes or case reports

## **Results**

Literature searching yielded 64 articles. After screening for exclusion criteria, 39 articles were selected for the analysis. Of these, two were on store-and-forward method, twenty eight were on real time video conferencing and nine were on remote monitoring. With regard to the disciplines involved there were nine in neurology, four each in psychiatry, diabetes and cardiology, three each in ophthalmology and dermatology, two each in acute care, transplant and ENT and one each in child abuse, endoscopy, general practice, leprosy, nephrology and radiology. According to Jovell and Navarro-Rubio classification there were three large sample RCTs, nine small sample RCTs, four prospective studies, three retrospective studies, one cohort study, four case control studies, and fifteen descriptive studies. Details of interventions and outcomes of twenty seven studies for each discipline group in descending order of strength are given in Table 2. Rest of the studies representing individual miscellaneous disciplines were excluded.

**Table 2.** Details of interventions and outcome of studies

<b>Discipline: Neurology (9 interventions)</b>			
Author/Ref	Sample	Intervention	Outcome
Meyer <sup>(5)</sup> 2007	400	telemedicine in the STRoKE DOC trial	It is feasible to perform site-independent stroke consultations
Ahmed <sup>(6)</sup> 2008	41	Epilepsy follow-up care through telemedicine	Follow-up care of epilepsy patients reduced patient costs, and improved patient satisfaction
Dallolio <sup>(7)</sup> 2008		Telerehabilitation in spinal injury	Benefited patients discharged from a spinal cord unit compared with standard care
Huijgen <sup>(8)</sup> 2008		Home-based telerehabilitation stroke, brain injury and m sclerosis.	Increased the efficiency of care.
Piron <sup>(9)</sup> 2009	36	Telerehabilitation	Early discharge from hospital was sustained by a telerehabilitation programme
Audebert <sup>(10)</sup> 2009	3060	Telemedicine in community hospitals for stroke	Telemedicine in community hospitals offers long-term benefit for acute stroke patients
Audebert <sup>(11)</sup> 2008	223	Mobile teleconsulting	Benefitted remote clinical decision-making
Meyer <sup>(12)</sup> 2008	234	Telemedicine in the STRoKE DOC trial	Telemedicine consultations resulted in more accurate decision making compared with telephone
Lutz <sup>(13)</sup> 2009	9	Home-telehealth for recovering from stroke	Innovative ways to target post-stroke rehabilitation programmes
<b>Discipline: Psychiatry (4 interventions)</b>			
Author/Ref	Sample	Intervention	Outcome
Kay-Lambkin <sup>(14)</sup> 2009	97	Computer-based psychological RX	Results similar to live intervention targeting both depression and substance
Mitchell <sup>(15)</sup> 2008		Cognitive-behavioural therapy via telemedicine versus face-to-face	Both were acceptable to participants and roughly equivalent in outcome to therapy
Kiropoulos <sup>(16)</sup> 2008	86	Internet-based CBT for panic disorder	Found to be comparable face-to-face and computer-based treatment
Myers <sup>(17)</sup> 2008	387	Adolescent telepsychiatry	Parents were highly satisfied with the care given for their children

<b>Discipline: Diabetes (4 interventions)</b>			
Author/Ref	Sample	Intervention	Outcome
Shea <sup>(18)</sup> 2009	1665	Telemedicine case management	Resulted in net improvements in HgbA1c, LDL-cholesterol and blood pressure levels over 5 years in medically underserved Medicare beneficiaries
Smith <sup>(19)</sup> 2008	633	Specialist telemedicine intervention	Did not significantly enhanced the value of CCM in primary care
Nikkanen <sup>(20)</sup> 2008	101	Teleconsultation.	Improved glucose and LDL cholesterol levels and blood pressure in patients
Izquierdo <sup>(21)</sup> 2009	41	School telemedicine	Improved diabetes care in grades kindergarten through eighth grade.
<b>Discipline: Cardiology (4 interventions)</b>			
Author/Ref	Sample	Intervention	Outcome
Scherr <sup>(22)</sup> 2009	120	Home based telemonitoring	Telemedical home surveillance group had reduced hospitalizations
Morgan <sup>(23)</sup> 2008		Home videoconferencing following congenital heart disease	Significantly reduced anxiety levels compared to telephone
Dowie <sup>(24)</sup> 2009	226	Paediatric telecardiology service for district hospitals	Reduced cost
Antonicelli <sup>(25)</sup> 2008		Home based telemonitoring	Associated with improvements in the composite endpoint of mortality and rate of hospitalizations
<b>Discipline: Ophthalmology (3 interventions)</b>			
Author/Ref	Sample	Intervention	
Helveston <sup>(26)</sup> 2008	270	Diagnosis and management of strabismus using telemedicine	Cases as viewed on telemedicine presented a true clinical picture.
Boucher <sup>(27)</sup> 2008	3050	Teleophthalmology screening project for diabetic retinopathy	Efficiently lowered barriers to screening and created new screening opportunities for a large number of known diabetic individuals who were lost to the traditional health system.
Lorenz <sup>(28)</sup> 2009	1222	Telemedical screening of retinopathy of prematurity	Showed the potential of a telemedical screening program.

<b>Discipline: Dermatology (3 interventions)</b>			
Author/Ref	Sample	Intervention	Outcome
Eminović <sup>(29)</sup> 2009	631	Teledermatologic consultation	Reducing referrals to a dermatologist by 20.7%.
Bergmo <sup>(30)</sup> 2009	98	Web-based consultations parents of children with atopic dermatitis	No effect of supplementing traditional treatment for childhood dermatitis with web-based consultations.
Edison <sup>(31)</sup> 1008	110	Store-and-forward tele dermatology	Confidence ratings for Live Interactive and Store and Forward were both statistically lower than In-Person examinations

### **Neurology**

Studies consisted of one large sample RCT, four small sample RCTs, one prospective trial and three case studies. The STROKE DOC study<sup>(5)</sup> which was a 5 year, 400 participant trial, comparing two modalities at four remote sites had shown that is feasible to perform site-independent stroke consultations. Small sample studies<sup>(6-9)</sup> and the prospective study<sup>(10)</sup> on tele-rehabilitation revealed increased efficiency of care, early discharge from hospital and long term benefit for stroke patients. Other three case studies<sup>(11-13)</sup> have presented innovative ways for post rehabilitation programmes.

### **Psychiatry**

The three retrospective studies<sup>(14-16)</sup> presenting computer based treatment for psychiatric disorders have shown that the outcome was found to be comparable to that of face-to-face methods. The case descriptive study<sup>(17)</sup> conducted on adolescent tele-psychiatry has concluded that parents were highly satisfied with the care given to their children.

### **Diabetes**

The other large sample RCT retrieved in this review<sup>(18)</sup> was the telemedicine case management on 1665 patients with usual care in older, ethnically diverse, medically under-served patients with diabetes mellitus which had resulted in net improvements in HgbA1c, LDL-cholesterol and blood pressure levels over a 5 year period in a group of medically under-served Medicare beneficiaries. The retrospective trial<sup>(19)</sup> based on delivering specialty advice did not reveal any reduction in diabetes related costs. Two other descriptive studies<sup>(20,21)</sup> reported favourable improvement in diabetes care due to by videoconferencing.

### **Cardiology**

Two prospective studies<sup>(22,23)</sup> on home based tele-monitoring in cardiac patients have shown that tele-medical home surveillance groups had reduced hospitalizations and significantly reduced anxiety levels compared to the control groups which did not receive the intervention. While a paediatric tele-cardiology service for district hospitals had reduced cost<sup>(24)</sup>, home based tele-monitoring was found to be associated with improvements in the composite endpoint of mortality and rate of hospitalizations<sup>(25)</sup>.

### **Ophthalmology**

A retrospective study<sup>(26)</sup> had shown that diagnosis and management of strabismus using telemedicine presented a true clinical picture. Tele-ophthalmology screening studies<sup>(27,28)</sup> have shown potential benefits.

### ***Dermatology***

The large sample RCT<sup>(29)</sup> on 631 subjects on Tele-dermatologic consultations has revealed reduced referrals to a dermatologist by 21%. A small sample RCT<sup>(30)</sup> using Web-based consultations on parents of children with atopic dermatitis revealed no effect of supplementing traditional treatment for childhood dermatitis. A descriptive study using store-and-forward tele-dermatology reported that confidence ratings for Live Interactive and Store and Forward were statistically lower than In-Person examinations<sup>(31)</sup>.

### ***Summary of outcome of reported telemedicine approaches***

Regarding relationship of outcome between conventional methods and telemedicine approaches, improvements in results were observed in 11 (41%) of the studies, which included three<sup>(6,8,9)</sup> from neurology, three<sup>(18,20,21)</sup> from diabetes, all four<sup>(22-25)</sup> from cardiology and one<sup>(29)</sup> from dermatology. Comparable results were seen in 4 (15%) studies, which included three<sup>(14-16)</sup> from psychiatry, and one<sup>26</sup> from ophthalmology. Benefits to patients were reported in 9 (33%), which included six<sup>(1,7,8,10-13)</sup> from neurology, one<sup>(17)</sup> from psychiatry and two<sup>(27,28)</sup> from ophthalmology. However three studies (11%) showed that telemedicine approach did not provide an enhanced benefit. They included a study in diabetes where specialist tele-medicine intervention did not augment Chronic Care Model (CCM) in primary care<sup>(19)</sup> and studies in dermatology where web based consultations had no effect of supplementing traditional treatment of childhood dermatitis. The dermatologists tested were more confident with in-person examinations than tele-dermatology.

### **Discussion**

Majority of studies published on telemedicine during the last two years have focused on neurology with psychiatry, diabetes and cardiology, in that order, followed by ophthalmology and dermatology.

Neurology studies which included five RCTs show the usefulness of telemedicine in this discipline. These have been applied in fields of stroke, epilepsy and rehabilitation. In Psychiatry, studies were small sample descriptive in nature and hence the outcome may have not been represented fully. The RCTs performed in diabetes have indicated a promising use of telemedicine for needy patients however a small study had reported negative results. All studies in cardiology have indicated successful implementation of home based surveillance. Retrospective studies on ophthalmology have shown advantages of tele-ophthalmology screening. The RCTs carried out in dermatology revealed advantages but a small sample study has reported some disadvantages of tele-medical systems over in-person examination. This agrees with previous recommendation that large scale RCTs are necessary in identifying health outcomes<sup>(3)</sup>.

### **Conclusions**

This review shows that most of the large sample high-end studies have confirmed advantages of telemedicine systems whereas small sample low-end studies have found it to be disadvantageous. It is necessary to perform further large sample randomized controlled trials on telemedicine interventions in all health related disciplines to confirm these results.

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