Assessment of the effectiveness of teledermatology has been hampered by the variety of outcome measures used, limiting the possibility for meta-analysis. This systematic mapping review classified the outcome measurement instruments used in randomized controlled trials of teledermatology conducted between 2008 and 2018 using the Core Outcome Measures in Effectiveness Trials taxonomy. Sixteen articles describing 12 studies were identified. Each trial used a mean of 3.7 outcome measurements (range 2–7), with a total of 55 different instruments employed. Most instruments mapped on the “skin and subcutaneous tissue outcomes” domain. The most frequently used instrument (Dermatology Life Quality Index) was used in only 3 studies. Over 60% of the instruments used did not cite any evidence of validation. This mapping review provides a list of outcome measurement instruments that can be used as a resource when designing teledermatology trials in the future and provides the foundation for the development of a core outcome set.

Key words: outcome measure; outcomes research; randomized controlled trial; teledermatology.

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Skin diseases are one of the most common reasons for patients to seek medical consultations (1). It is also recognized that there is a shortage of healthcare professionals with the relevant skills (2). Dermatology, because of its visual character, is well suited to telemedicine for patient consultations, referrals and triage, which has the potential to increase accessiblility to dermatological expertise, maximize work-force potential, improve patient health outcomes, and reduce costs (3). Teledermatology consultations can be “store and forward”, with electronic digital images sent to review at a later time (also referred to as asynchronous), live and interactive (synchronous) or a combination of both (3). Literature reviews of teledermatology service evaluations have reported positive impacts, such as more rapid diagnoses (4), improved cost-effectiveness (5, 6), but also some negative impacts, such as increased referrals to secondary care (7). Systematic literature reviews of randomized controlled trials (RCTs) of telemedicine tend to be more reserved about potential benefits because of the heterogeneity in quality, design, conditions and outcomes of the studies, which in turn limits the ability to pool data (8–10).

The lack of standardization of outcome measurement instruments is a recurrent challenge when making evidence-based decisions to optimize patient care. However, this problem tends to persist, because within a tight project timeline, researchers may not have the resources to assess the range of outcome measurement instruments used previously, or to identify those that would enable direct comparisons with previous work. To address this issue the Core Outcomes Measures in Effectiveness Trials (COMET) Initiative (http://www.comet-initiative.org/) is now encouraging researchers to develop and adopt the use of evidence-based core outcome sets (COS) (11). These are agreed standardized sets of outcomes that the COMET Initiative recommends to be measured and reported as a minimum in all clinical trials in a particular condition or context (12). They may also be used in audit or other forms of research. A taxonomy to classify outcomes has also been developed by the COMET Initiative, to standardize the classification of all outcomes reported. This taxonomy is also used in the classification of outcomes in COS, which further encourages the standardized reporting of outcomes (11). One important step in the development of a COS for a particular field is to identify outcome measurement...
instruments used previously in order to generate a long list of outcomes that can be considered candidates for inclusion into a particular COS (13). This is typically followed by some form of consensus-seeking process (such as an e-Delphi followed by a consensus meeting of all interested stakeholders) with the ultimate goal of agreeing on a COS (11). This study has been designed to identify and categorize the outcome measurement instruments reported in RCTs of teledermatology interventions.

METHODS

Inclusion and exclusion criteria

This systematic mapping review protocol defined study inclusion criteria as RCTs, cluster randomized controlled or quasi-randomized trials of teledermatology interventions in which participants were patients presenting with dermatological problems. The study findings had to be published as peer-reviewed, full-text articles within the last 10 years. Studies with teledermatology services as an intervention and standard care as the control group were included. Articles were not limited to the English language or to any particular age group.

Systematic reviews, editorials, commentaries or letters were excluded. Similarly, articles were also excluded if they focused on the evaluation of a technology or a device without patient involvement, or if the intervention used was not teledermatology; for example, outreach consultant care or general practitioners (GPs) with a special interest in dermatology.

Search strategy

The search strategy was developed with the medical librarians at the Lee Kong Chian School of Medicine (Table S1) and conducted in November 2018. MEDLINE, EMBASE, CINAHL, PubMed, and Scopus were searched for articles published between 1 January 2008 and 31 December 2018. The search was complemented by hand-searching of trial registries (e.g. Clinicaltrials.gov), targeted journals (e.g. Journal of Telemedicine and Telecare, Telemedicine Journal and e-Health), the Cochrane Controlled Register of Trials, and the reference lists of all eligible studies.

Eligibility assessment

Two reviewers (AC and CS) independently screened the titles and abstracts for eligibility based on the above selection criteria. Where consensus of eligibility was not reached a third reviewer, (HES or ChA) was consulted. Full texts were obtained for all selected studies, and if study eligibility remained unclear it was again discussed with a third reviewer.

Data extraction

Characteristics of the studies (i.e. year published, study setting, country, skin disease studied, age and sex of participants), outcome reported, type of outcome reported (i.e. primary or secondary), outcome measurement instrument used, and the remarks about the validity of the outcome measurement instrument made by the studies authors’ were extracted from the eligible papers. Outcomes were mapped onto the taxonomy developed by the COMET initiative (12). If an outcome was composite and addressed several domains it was classified within each of the relevant domains.

RESULTS

Studies and study characteristics

After duplicates were removed, 460 potentially eligible records were identified and screened according to the protocol (Fig. 1). A final total of 16 articles based on 12 studies were included in this review. Data were extracted from all the articles, with one exception, an article in Dutch (14) that reported the same results from a study that had been published previously in English (15). Most of the studies included in this mapping review were conducted in the USA (64.3%) and the rest in Europe (i.e. Austria, France, Norway, Switzerland, and The Netherlands). The study characteristics of the studies were as follows: a total of 2,993 participants were recruited (ranging from 64 to 698 participants per study). The mean age of participants ranged from 2.7 to 63 years (but only 9 studies reported this). In the 10 studies that reported the sex of participants, slightly more men (54.3%) were included than women (45.7%). Full details are shown in Table I.

Outcome measurement instruments

The total number of outcome measurement instruments used was 55, with a mean of 3.7 in each article (range 2–7). Twenty-four of the outcome measurement instruments were categorized in the Life Impact COMET Core Area, with 2 of these outcome measurement instruments also categorized in the Resource Use COMET Core Area. Seventeen outcome measurement instruments were categorized in the Physiological/clinical COMET Core Area. Seventeen outcome measurement instruments were categorized in the Resource Use COMET Core Area.
Table I. Characteristics of studies

| Study | Design | Setting | Skin disease under study | Age range (years) | Mean age (years) | Female (%) of sample |
|-------|--------|---------|-------------------------|------------------|-----------------|---------------------|
| A. Chow et al. (2015) | Research study office | Dermatologist clinic | Atopic dermatitis | Not reported | Control=28.0, Treatment=27.4 | 55.8 |
| Armstrong, et al. (2015) | Secondary care hospital | University dermatology outpatient clinic and Medical Centre | Atopic dermatitis | Not reported | Control (children)=2.7, Treatment (children)=2.9, Control (adults)=32.1, Treatment (adults)=30.9 | Not reported |
| Bergmo, et al. (2009) | Research study office | Dermatologist clinic | Atopic dermatitis | Control (children)=4.2–6.3, Treatment (children)=4.6 | Control (parents)=34.0–37.6, Treatment (parents)=31.3–34.5 | 55.8 |
| Chambers, et al. (2012) | Research study office | Dermatologist clinic | Psoriasis | Not reported | Control=43.2, Treatment=51.0 | 42.2 |
| Datta, et al. (2015) | Primary care clinic | Veteran Affairs hospitals | Ambulatory skin conditions | Not reported | 62.3, 2.3 | 32.1 |
| Eminović, et al. (2015) | Research study office | Dermatologist clinic | Acne | Not reported | Control (GP)=Not reported, Treatment (GP)=Not reported | Not reported |
| Ford, et al. (2018) | Research study office | Hospital | Psoriasis | Not reported | Control=28.0, Treatment=27.5 | 71.5 |
| Frühauf, et al. (2015) | Research study office | University dermatology outpatient clinic | Acne | Not reported | 53.9, 2.3 | 55.1 |
| Kornmehl, et al. (2017) | Research study office | Dermatologist clinic | Atopic dermatitis | Not reported | Control=28.0, Treatment=27.4 | 3.3 |
| Pak, et al. (2009) | Research study office | Army medical dermatology clinic | Atopic dermatitis | Not reported | Control=62.9, Treatment=61.7 | 7.3 |
| Piette, et al. (2017) | Research study office | GP clinics | No specific skin disease | Control=43.5, Treatment=44.4 | Control (children)=2.7, Treatment (children)=2.9 | 5.6 |
| Tandjung, et al. (2015) | Research study office | Institute of Primary Care | No specific skin disease | Not reported | Control=2.7, Treatment=2.9 | 5.6 |
| van Os-Medendorp, et al. (2012) | Research study office | University dermatology outpatient clinic | No specific skin disease | Control (children)=2.7, Treatment (children)=2.9 | Control (adults)=32.1, Treatment (adults)=30.9 | 5.6 |
| Watson, et al. (2013) | Research study office | Hospital | No specific skin disease | Control=28.0, Treatment=27.5 | Not reported | 5.6 |

Outcomes and outcome domains

The total number of primary and secondary outcomes reported in the 16 articles was 44; hence the mean number of outcomes reported was 2.9. Slightly over half (53.3%) of the articles differentiated between primary and secondary outcomes. From these studies, 11 primary outcomes and 23 secondary outcomes were reported. A total of 21 outcomes were reported in the studies that did not differentiate between primary or secondary outcomes.

As shown in Fig. 2, when mapped on the COMET taxonomy the “Skin and subcutaneous tissue outcomes” outcome domain had the largest number of outcome measurement instruments mapped in it (i.e. 34.5%). This domain is in the “Physiological/clinical skin” COMET Core Area, which includes physiological symptoms and functioning (12). Despite having the highest frequency, the relatively low percentage in this domain reflects the heterogeneity of the outcome measurement instruments reported in the studies. The most common outcome measurement instrument used that was mapped in this domain was the “Investigator Global Assessment”. The second most commonly mapped COMET outcome domain was “Delivery of Care” (i.e. 21.8%), and this domain is in the “Life Impact” Core Area. Only one of the outcome measurement instruments mapped in this domain was validated; this was the Dutch translation of the Patient Satisfaction Questionnaire III, which was modified and revalidated because only 20 out 43 questionnaire items were used. The third most commonly mapped COMET domain was “Economic” (i.e. 14.5%), and this is in the “Resource Use” COMET Core Area. The most
Table II. Outcomes, outcome measurement instruments, and Core Outcomes Measures in Effectiveness Trials (COMET) categories

| Outcome | Primary or secondary outcome | Outcome measurement instrument | Validity* COMET Core Area | COMET Outcome Domain |
|---------|-----------------------------|--------------------------------|--------------------------|---------------------|
| Cost minimization analysis of a store-and-forward teledermatology consult system (3) | Clinical outcomes | Primary | Dermatologist would rate two sets of images as "worse, no change or improved". | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Direct costs | Not specified | Costs of clinic visits, teledermatology encounters, radiology procedures, laboratories, preparations, and medications (in US$). | None | Resource use | Economic |
| Indirect costs | Secondary | Lost productivity calculated at the hourly wage rate of US$15.73. | None | Resource use | Economic |
| Teledermatological consultation and reduction in referrals to dermatologists: a cluster randomized controlled trial (15) | Preventable consultations | Primary | The face-to-face dermatology consultation was considered preventable if the GP treatment was successful. | None | Resource use | Economic |
| Patient satisfaction | Secondary | Patient Satisfaction Questionnaire III (Dutch translated version) – Modified version (20 out of 43 items used) | T1 | Life impact | Delivery of care |
| Patient-centred, direct-access online care for management of atopic dermatitis a randomized clinical trial (16) | Disease severity (patient rated) | Not specified | Patient-Oriented Dermatitis Measure (POEM) | T2 | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Disease severity (physician rated) | Not specified | Investigator Global Assessment (IGA) | a | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Mobile teledermatology helping patients control high-need acne: a randomized controlled trial (17) | Disease severity | Not specified | Global Acne Severity Scale | T3 | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Disease severity | Not specified | Total lesion counting | T4 | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Perceived benefit from treatment (patient rated) | Not specified | Patient Benefit Index – Modified version | T5 | Life impact | Perceived health status |
| Patient satisfaction | Not specified | 15-item satisfaction questionnaire | T6, T7 | Life impact | Delivery of care |
| Access to dermatological care with an innovative online model for psoriasis management: results from a randomized controlled trial (18) | Access to care | Not specified | Distance travelled to appointment | T8, T9 | Life impact | Delivery of care |
| Access to care | Not specified | Waiting time for transportation and in-office appointments | T10, T11 | Life impact | Delivery of care |
| Feasibility and diagnostic accuracy of teledermatology in Swiss primary care: process analysis of a randomized controlled trial (19) | Feasibility | Not specified | Likert scale ratings of 4 questions about the use of a smartphone alternatively to the digital camera, technical problems with the camera, problems with the transmission of the images or with the process of sending patient information together with images to the study centre. | None | Life impact | Delivery of care |
| Feasibility | Not specified | Number of photographs with adequate quality that allowed dermatologists to feedback on the skin condition. | None | Resource use | Economic |
| Diagnostic accuracy | Not specified | The number of preventable dermatologist consultations and as proportion of dermatologist-reported malignancies. | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Web-based consultations for parents of children with atopic dermatitis: results of a randomized controlled trial (24) | Use of web consultations | Not specified | Number of messages sent by parents to the consultation website. | None | Resource use | Economic |
| Self-management behaviour | Not specified | Self-reported number and frequency of skin care treatments performed by parents per week. | None | Resource use | Societal/carer burden |
| Disease severity (physician rated) | Not specified | Physician rated severity Scoring of Atopic Dermatitis (SCORAD) | T12 | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Resource use | Not specified | Patient reported number of visits to emergency ward, GPs, complementary therapists, outpatient consultations, hospital admissions, personal expenses (e.g. moisturisers, special clothing, diets, parent’s absence from work). | None | Resource use | Economic, Hospital, Need for further intervention, and Societal/carer burden |
| Web-based consultations for parents of children with atopic dermatitis: results of a randomized controlled trial (25) | Disease severity (physician rated) | Primary | Psoriasis Area Severity Index (PASI) | T13 | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Disease severity (physician rated) | Primary | Investigator Global Assessment (IGA) | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Quality of life (specific) | Secondary | Dermatology Life Quality Index (DLQI) | T14 | Life impact | Physical functioning, Social functioning, Role functioning, and Emotional functioning/ wellbeing |
| Cost and utility analysis of a store-and-forward teledermatology referral system: a randomized clinical trial (26) | Direct costs | Not specified | Costs incurred for teledermatology intervention cost, dermatology visit costs, dermatology medication costs, reimbursed travel costs (in US$). | None | Resource use | Economic |
| Indirect costs | Not specified | Travel costs, loss of productivity, dermatology care sought outside the VA system. | None | Life impact, Resource use | Role functioning, Economic, and Need for further intervention Perceived health status |
| Utility | Not specified | Time trade-off (e.g. "If you could live the next 20 years with your current skin condition or 19 years with perfect health, which would you choose?") | None | Life impact | Perceived health status |
Table II: Contd

| Outcome | Primary or secondary outcome | Outcome measurement instrument | Validity* COMET Core Area | COMET Outcome Domain |
|---------|-----------------------------|--------------------------------|--------------------------|----------------------|
| Direct-access online care for the management of atopic dermatitis: a randomized clinical trial examining patient quality of life (27) | | | | |
| Quality of life (specific) | Not specified | Dermatology Life Quality Index (DLQI) | c | Life impact | Physical functioning, Social functioning, Role functioning, and Emotional functioning/ wellbeing |
| Quality of life (specific) | Not specified | Children’s Dermatitis Life Quality Index (CDLQI) | c | Life impact | Physical functioning, Social functioning, Role functioning, and Emotional functioning/ wellbeing |
| Health status | Not specified | Short Form questionnaire (SF-12) | None | Life impact | Perceived health status |
| Impact of a store-and-forward teledermatology intervention vs usual care on delay before beginning treatment: a pragmatic cluster-randomized trial in ambulatory care (28) | | | | |
| Time taken for dermatologist’s advice consultations | Primary | Number of days between initial consultation and dermatologist consultation. | None | Life impact | Delivery of care |
| Preventable dermatology consultations | Secondary | The number of teledermatology requests for which the dermatologist did not need to see the patient in person. | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Satisfaction (patient rated) | Secondary | Two questions using Likert scale with 4-items about global and time-to-treatment satisfaction. | None | Life impact | Delivery of care |
| Satisfaction (doctor rated) | Secondary | Two questions using Likert scale with 4 items global and time-to-treatment satisfaction. | None | Life impact | Delivery of care |
| Quality of photographs | Secondary | Number of photographs the dermatologist considered insufficient quality to assess condition. | None | Resource use | Economic |
| E-health in caring for patients with atopic dermatitis: a randomized controlled cost-effectiveness study of internet-guided monitoring and online self-management training (29) | | | | |
| Quality of life (specific) | Primary | Dermatology Life Quality Index (DLQI) for adults | T14, T15 | Life impact | Physical functioning, Social functioning, Role functioning, and Emotional functioning/ wellbeing |
| Quality of life (specific) | Primary | Infants’ Dermatitis Quality of Life Index (IDQOL) for children/parent | T16, T17 | Life impact | Physical functioning, Social functioning, Role functioning, and Emotional functioning/ wellbeing |
| Disease severity | Primary | Two parts of the (shortened) “Impact of Chronic Skin Disease on Daily Life” questionnaire. | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Intensity of symptoms | Primary | Visual analogue scale (VAS) measuring the itch intensity. | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Direct costs | Secondary | Multiplying actual resource utilisation with unit costs. | None | Resource use | Economic |
| Indirect costs | Secondary | Estimated using two modules online of the “Health and Labour Questionnaire” and by applying the friction cost approach to account for reduced productivity during paid work and unpaid labour. | None | Resource use | Economic and Societal/ carer burden |
| Costs of care | Secondary | Written diary (Month 3, Month 12 post-randomization) | None | Resource use | Role functioning and Societal/carer burden |
| A randomized trial to evaluate the efficacy of online follow-up visits in the management of acne (30) | | | | |
| Disease severity | Primary | Total Inflammatory Lesion Count (TILC) | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Change in disease severity | Secondary | Frontal Inflammatory Lesion Count (FILC) | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Change in disease severity | Secondary | Burke and Cunliffe Leeds technique | T18 | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Change in disease severity | Secondary | Forced choice | None | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Satisfaction with care (patient rated) | Secondary | Survey | T19d | Physiological/clinical | Skin & subcutaneous tissue outcomes |
| Satisfaction with care (physician rated) | Secondary | Survey | T19d | Life impact | Delivery of care |
| Time required to complete a visit (patient rated) | Secondary | Time taken to complete a visit recorded by a research team member using a stopwatch. | None | Life impact | Delivery of care |
| Time required to complete a visit (physician rated) | Secondary | Time taken to complete a visit as measured by the physician using a stopwatch. | None | Life impact | Delivery of care |
| Effect of store and forward teledermatology on quality of life: a randomized controlled trial (31) | | | | |
| Quality of life (specific) | Primary | Skindex-16 | T20 | Life impact | Global quality of life |
| Health status | Secondary | SF-12 v2 | T21 | Life impact | Global quality of life |
| Co-morbidity | Secondary | A comorbidities checklist that recorded chronic medical conditions, allergies, and any over-the-counter or prescription medications. | None | Physiological/clinical | General outcomes |
| Satisfaction (patient rated) | Secondary | One question assessing satisfaction with care received for the skin condition. | None | Life impact | Delivery of care |
common outcomes in this domain were direct costs and indirect costs.

Validation

Of the 55 outcome measurement instruments, 61.8% did not have citations of validation in the study publication.

Safety outcomes

There were no specific safety outcomes measured in the studies; however, 4 studies briefly mentioned issues about safety and adverse events. One study reported that participants could report any adverse events that occurred on a standardized questionnaire used during the trial (16). Another study, which involved isotretinoin therapy for acne, reported that some of the questions were validated previously.

T16. Lewis-Jones MS, Finlay AY, Dykes PJ. The Infants’ Dermatitis Quality of Life Index. Br J Dermatol 2001; 144: 104–110.

Heterogeneity of outcome measurement instruments

There were 44 outcomes reported, and the majority of outcomes were categorized as skin and subcutaneous tissue outcomes. This finding is similar to what was found in another systematic review that identified and grouped outcomes of dermatology-related RCTs (20). Of the 55 outcome measurement instruments used to measure these outcomes, only 3 of these instruments were reported in different articles. This highlights the heterogeneity of outcome measurement instruments found in this review has also been reported in other systematic reviews (21, 22).

Validation of outcome measurement instruments

Over 60% of the reported outcome measurement instruments did not have any citation to a validation study. It was beyond the scope of this review to explore further
the rigour of the validation of the outcome measurement instruments. Citing the validation or development references, helps the clinical and scientific community to make informed decisions about the outcome measurement instruments they can use for their own clinical use and research studies.

**Safety**

There were no specific safety outcomes measured in the reviewed trials, but 4 studies briefly mentioned issues about safety and adverse events. While safety may not be of great importance in studies focusing only on teledermatology referral processes, when the study includes treatment or procedures then safety is increasingly important. The Patient-Reported Outcomes Safety Event Reporting Consortium Guidance could be used to guide such a practice in the future (23).

**Strengths and limitations**

The results from this mapping review provide novel and valuable information about outcome measurement instruments that clinicians and researchers can use to make informed decisions about which outcome measurement instrument to use for treatment and research studies. Specifically, we have generated a list of the outcome measurement instruments used in recent RCTs of teledermatology and the reported validity of each measure. This information will provide a ready resource of outcome measurement instruments for researchers of teledermatology in the future. These data may also inform the process of developing a core outcome set in the future.

The current review has some limitations. First, the search was limited to trials published in the last decade. While this ensures an up-to-date overview of recent trials, many studies were excluded, as the rate of teledermatology trials conducted was low in the inclusion period of this review. Secondly, the current review excluded unpublished research reports and conference abstracts, in which additional outcome measurement instruments might have been found. Thirdly, an in-depth analysis of the validity of outcome measurement instruments used was not undertaken. The scope of this mapping review was constrained by the resources available, but future reviews could expand the current review to address the second and third limitations.

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