REVIEW ARTICLE

Outcome Measurements Used in Randomized Controlled Trials of Teledermatology: A Systematic Mapping Review

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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.

Accepted Sep 10, 2019; E-published Sep 10, 2019

Acta Derm Venereol 2019; 99: 1210–1217.

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SIGNIFICANCE

Assessment of the effectiveness of teledermatology is challenging due to different outcome measurements utilized. This review mapped 55 different outcome measurements reported in clinical trials of teledermatology using the Core Outcome Measures in Effectiveness Trials taxonomy. Each trial used a mean of 3.7 measurements (range 2–7), and most measurements measured "skin and subcutaneous tissue outcomes". The most frequently used measurement was used in only 3 studies. Over 60% of the measurements did not cite evidence of validation. This review provides a list of measurements for use in designing future teledermatology trials, and provides the foundation to develop a core outcome set.

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 accessibility 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

doi: 10.2340/00015555-3312
Acta Derm Venereol 2019; 99: 1210–1217

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 SI[1]) 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.

[1]https://doi.org/10.2340/00015555-3312

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

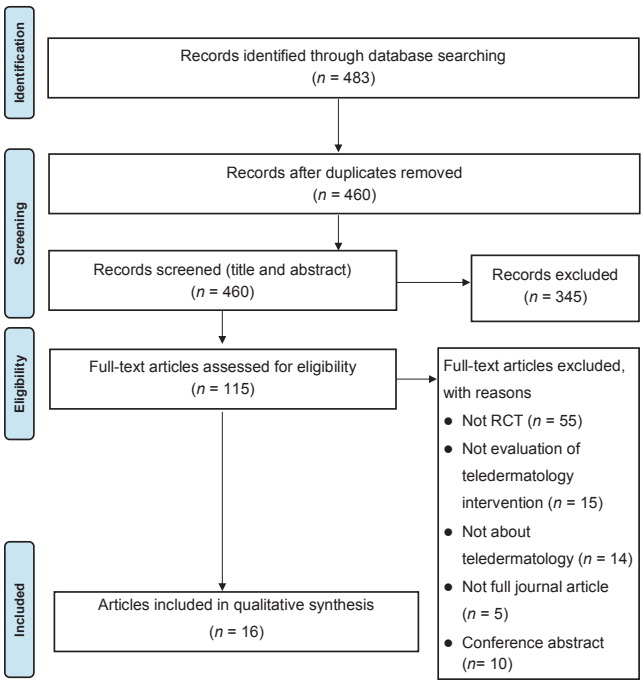

Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. RCT: randomized controlled trial.

Table I. Characteristics of studies

				Skin disease under study	Age range (years)	Mean age (years)	Female (% of sample)
Armstrong, et al. JAMA Dermatol (16)	2015	Research study office	USA	Atopic dermatitis	Not reported	Control=28.0 Treatment=27.4	55.8
Bergmo, et al. Acta Paediatr (24)	2009	Secondary care hospital	Norway	Atopic dermatitis	Control (children)=4.3–6.3 Treatment (children)=3.7–5.5 Control (parents)=34.0–37.6 Treatment (parents)=31.3–34.5	Control (children)=5.3 Treatment (children)=4.6 Control (parents)=35.8 Treatment (parents)=32.9	55.1
Chambers, et al. J Am Acad Dermatol (25)	2012	Dermatologist clinic	USA	Psoriasis	Not reported	Control=43 Treatment=51	42.2
Datta, et al. JAMA Dermatol (26)	2015	Veteran Affairs hospitals	USA	Ambulatory skin conditions	Not reported	62.3	2.3
Eminović, et al. Arch Dermatol (15)	2009	Dermatologist clinic	The Netherlands	No specific skin disease	Not reported	Control (GP)=Not reported Treatment (GP)=Not reported Control (patients)=44 Treatment (patients)=42	56.4
Ford, et al. Telemed J E Health (18)	2018	Outpatient clinic	USA	Psoriasis	Not reported	49	49.7
Frühauf, et al. J Eur Acad Dermatol Venereol (17)	2015	Medical university clinic	Austria	Acne	13–37	Mean age not reported, but median age was reported as 20 years.	36.2
Kornmehl, et al. Telemed J E Health (27)	2017	Dermatologist clinic	USA	Atopic dermatitis	Not reported	Control=28.0 Treatment=27.4	55.8
Pak, et al. Telemed J E Health (3)	2009	Army medical dermatology clinic	USA	Atopic dermatitis	Not reported	Not reported	Not available
Piette, et al. J Telemed Telecare (28)	2017	GP clinics	France	No specific skin disease	Control=19–78 Treatment=19–81	Control=43.5 Treatment=44	60.2
Tandjung, et al. J Eval Clin Pract (19)	2015	Institute of Primary Care	Switzerland	No specific skin disease	Not reported	Not reported	Not available
van Os-Medendorp, et al. Br J Dermatol (29)	2012	University dermatology outpatient clinic and Medical Centre	The Netherlands	Atopic dermatitis	Not reported	Control (children)=2.7 Treatment (children)=2.9 Control (adults)=32.1 Treatment (adults)=30.9	52.8
Watson, et al. Arch Dermatol (30)	2010	Hospital	USA	Acne	Not reported	Control=28.0 Treatment=27.5	71.5
Whited, et al. JAMA Dermatol (31)	2013	Veteran Affairs hospitals	USA	No specific skin disease	Not reported	Control=62.9 Treatment=61.7	2.3
Whited, et al. J Telemed Telecare (32)	2013	Veteran Affairs hospitals	USA	No specific skin disease	Not reported	Control=63 Treatment=62	2.3

Area, and 11 were in the Resource Use COMET Core Area. The heterogeneity of outcome measurement instruments identified in this review is further exemplified by the fact that the Dermatology Life Quality Index (DLQI), which was the most commonly cited outcome measurement instrument, represented only 3 (5.5%) out of 55 outcome measurement instruments. These details are further detailed in **Table II**.

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	Secondary	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 Eczema 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[b]	Life impact	Delivery of care
Access to care	Not specified	Waiting time for transportation and in-office appointments	T10, T11[b]	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
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 Dermatology 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	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 of 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. This includes costs of the e-health service and the costs of outpatient visits.	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	Life impact, 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	T19[d]	Physiological/clinical	Skin & subcutaneous tissue outcomes
Satisfaction with care (physician rated)	Secondary	Survey	T19[d]	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

Table II. Contd

Outcome	Primary or secondary outcome	Outcome measurement instrument	Validity*	COMET Core Area	COMET Outcome Domain
Clinical course outcomes for store and forward teledermatology vs conventional consultation: a randomized trial (32)					
Physician Assessment of Change (Global)	Secondary	Five-point rating scale (i.e. Resolved, Improved, Unchanged – not clinically relevant, Unchanged – clinically relevant, or Worse, or Unable to evaluate.	None	Physiological/clinical	Skin & subcutaneous tissue outcomes
Physician Assessment of Change (Global)	Secondary	Clinical course rating (i.e. Favourable, or Not-Favourable)	None	Physiological/clinical	Skin & subcutaneous tissue outcomes

*Authors' remarks about validity of outcome measurement instrument.
[a]Authors mentioned that the IGA is validated, but listed studies that used the IGA instead of the validation study of IGA. [b]References cited by author only for the Medical Expenditure Panel Survey. [c]Authors report that this outcome measurement tool has been validated, but no references of validation provided were provided. [d]The authors reported that some of the questions were validated previously.
Reference cited by the author for this outcome measurement tool:
T1. Hagedoorn M, Uijl SG, Van Sonderen E, Ranchor AV, Grol BM, Otter R, Krol B, Van den Heuvel W, Sanderman R. Structure and reliability of Ware's Patient Satisfaction Questionnaire III: patients' satisfaction with oncological care in the Netherlands. Medical Care 2003; 41: 254–263.
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T3. Dreno B, Poli F, Pawin H, Beylot C, Faure M, Chivot M, Auffret N, Moyse D, Ballanger F, Revuz J. Development and evaluation of a Global Acne Severity scale (GEA scale) suitable for France and Europe. J Eur Acad Dermatol Venereol 2011; 25: 43–48.
T4. Balaji A, Rashmi K, Devinder MT. Scoring systems in acne vulgaris. Ind J Dermatol Venereol Leprol 2009; 75: 323.
T5. Augustin M, Reich C, Schaefer I, Zschocke I, Rustenbach SJ. Development and validation of a new instrument for the assessment of patient-defined benefit in the treatment of acne. Journal der Deutschen Dermatologischen Gesellschaft 2008; 6: 113–120. NB: The version used in this study was modified.
T6. Eminović N, Witkamp L, de Keizer NF, Wyatt JC. Patient perceptions about a novel form of patient-assisted teledermatology. Arch Dermatol 2006; 142: 647–651.
T7. Frühauf J, Schwantzer G, Ambros-Rudolph CM, Weger W, Ahlgrimm-Siess V, Salmhofer W, Hofmann-Wellenhof R. Pilot study on the acceptance of mobile teledermatology for the home monitoring of high-need patients with psoriasis. Austral J Dermatol 2012; 53: 41–46.
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T10. Agency for Healthcare Research and Quality. Access to care measures. 2013. Available from: www.ahrq.gov/research/findings/nhqrdr/nhdr02/premeasurea.html
T11. MEPS Access to Care Supplement-P15R5/P16R3/P17R1. 2013. Available from: http://meps.ahrq.gov/survey_comp/hc_survey/2011/AC110311.pdf.
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T13. Feldman SR, Krueger GG. Psoriasis assessment tools in clinical trials. Annals Rheumat Dis 2005; 64 (Suppl 2):ii65–ii68. discussion ii9–73.
T14. Basra MK, Fenech R, Gatt RM, Salek MS, Finlay AY. The Dermatology Life Quality Index 1994–2007: a comprehensive review of validation data and clinical results. Brit J Dermatol 2008; 159: 997–1035.
T15. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI) – a simple practical measure for routine clinical use. Clin Exper Dermatol 1994; 19: 210–216.
T16. Lewis-Jones MS, Finlay AY, Dykes PJ. The Infants' Dermatitis Quality of Life Index. Br J Dermatol 2001; 144: 104–110.
T17. Beattie PE, Lewis-Jones MS. An audit of the impact of a consultation with a paediatric dermatology team on quality of life in infants with atopic eczema and their families: further validation of the Infants' Dermatitis Quality of Life Index and Dermatitis Family Impact score. Brit J Dermatol 2006; 155: 1249–1255.
T18. Burke BM, Cunliffe WJ. The assessment of acne vulgaris: the Leeds technique. Br J Dermatol 1984; 111: 83–92.
T19. Eminović N, Witkamp L, de Keizer NF, Wyatt JC. Patient perceptions about a novel form of patient-assisted teledermatology. Arch Dermatol 2006; 142: 648–649.
T20. Chren MM, Lasek RJ, Quinn LM, Mostow EN, Zyzanski SJ. Skindex, a quality-of-life measure for patients with skin disease: reliability, validity, and responsiveness. J Investig Dermatol 1996; 107: 707–713.
T21. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical Care 1996; 34: 220–233.

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 participants, collected reports of adverse reactions from clinicians during face-to-face or online consultations, depending on which experimental group the participant was allocated into (17). Two other studies mentioned safety only as part of the discussion of their results (18, 19).

DISCUSSION

To the best of our knowledge, this is the first systematic review of outcomes and outcome measurement instruments reported in teledermatology RCTs. Sixteen articles from 12 eligible studies were included in this review. It was notable that the included studies were either from Europe or from the USA.

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 used in RCTs of teledermatology, and questions the comparability of these trials. 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

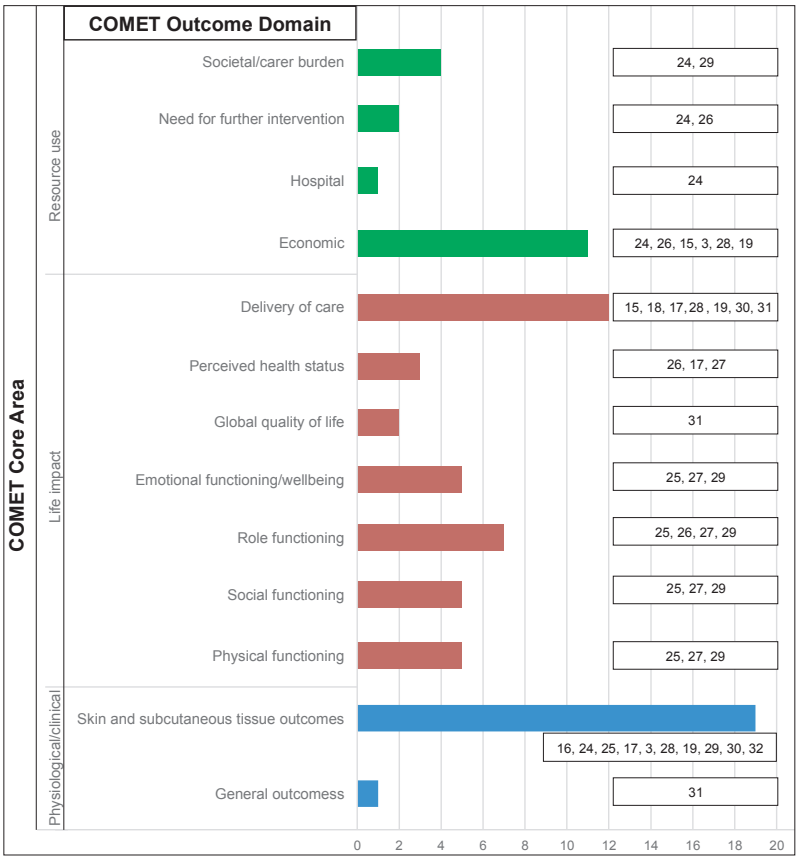

Fig. 2. Core Outcomes Measures in Effectiveness Trials (COMET) Core Areas and Outcome Domains.

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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