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Treatment effect of individual video consultation vs inperson consultation in mood, anxiety and personality disorders: a protocol for a systematic review and metaanalysis

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ADMINISTRATIVE INFORMATION

Title Treatment effect of individual video consultation *vs* in-person consultation in mood, anxiety and personality disorders: a protocol for a systematic review and meta-analysis

Registration This protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 2 July 2021 (Registration number CRD42021256357)

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Amendments Any deviation from the initial protocol during the review process will be documented in PROSPERO registry and reported in the final report.

Word Count 2800

ABSTRACT

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Introduction Major advancements in technology has led to considerations how video consultation (VC) and other technology platforms can be meaningfully integrated in treatment for psychiatric disorders. The COVID-19 pandemic has placed a further focus on use of VC in psychiatry. Despite the widespread use of VC, little is known about its effect compared to traditional in-person (IP) consultation. The objective of this systematic review is to examine if individual psychiatric outpatient interventions for adults conducted using VC are comparable to IP in terms of (1) psychopathology outcomes, (2) levels of patient satisfaction, (3)working alliance, and (4) dropout from treatment.

Methods and analysis This review will only include randomized controlled trials. Adult participants with mood disorders, anxiety, or personality disorders will be included in the review. The primary outcome is psychopathology, and secondary outcomes include patient satisfaction, treatment alliance, and dropout rate. Systematic searches were conducted in MEDLINE, APA PsycINFO, Embase, Web of Science, and CINAHL. The inverse-variance method will be used to conduct the meta-analysis. Effect sizes will be calculated as standardized mean difference (Hedges'g) for the primary outcome, mean difference (MD) for patient satisfaction and working alliance, and risk ratio (RR) for the dropout rate. Effect sizes will be supplemented with 95% CI. We will calculate the I² statistic to quantify heterogeneity and Chi2 statistic (χ^2) to test for heterogeneity for the primary outcome. Potential clinical and methodological heterogeneity moderators will be assessed in subgroup and sensitivity analysis. The risk of bias will be assessed by Cochrane Risk of Bias Tool 2, and confidence in cumulative evidence will be assessed by GRADE.

Ethics and dissemination No ethical approval is required for this systematic review protocol. The findings of this study will be published in a peer-review scientific journal.

PROSPERO registration number CRD42021256357 Y.C.

Article summary

Strengths and limitations of this study

- This study review exclusively include randomized controlled trials to compare individual psychiatric • treatment using VC to IP treatment
- This review will specifically examine individual treatment for mood, anxiety, or personality disorder •
- Validated and standardized measures will be used to assess psychopathology, client satisfaction with • treatment (CSQ-8) and working alliance (WAI) across all the studies.
- This systematic review will examine dropout rates across treatment formats not previously examined • in other systematic reviews
- Due to the rigid eligibility criteria regarding study design, participants, interventions, comparator, • and outcomes measures, studies not meeting the inclusion criteria will be excluded.

INTRODUCTION

Video consultation (VC) is a virtual consultation where the communication is synchronous (occurs in realtime) while the patient and clinician are in different physical locations. Various names have been suggested and used interchangeably in the scientific literature to describe VC. Telehealth, telepsychiatry, telemental health, and teleconsultation, for example, are commonly used. Telemedicine (healing at a distance) is the broader term and encompasses these different applications.¹²

Experimentation with VC in medical settings first began in the 1950s. These studies were based on a simple two-way closed-circuit television and VC was used for treatment and education purposes.³ Advances in technology and increasing access to the internet mean that VC can now be quickly accessed using a smartphone or other digital devices.^{4 5 6} Additionally, the COVID-19 pandemic has led to the accelerated use of digital solutions in health care systems in many countries.^{7 8 9}

The use of VC in mental health services has several potential advantages, which include making services more accessible and flexible, reducing the cost of transport and time, reducing stigma, promoting patient autonomy, and providing an opportunity for people with mental health difficulties to engage with services if they find it challenging to attend in-person (IP) consultations.¹⁰ ¹¹

There are also some potential disadvantages of VC, which include concerns about data security, technical obstacles, questions regarding the efficacy of interventions grounded in VC and which patient groups VC is most suitable for, concerns about establishing good working alliances, maintaining treatment engagement, and the allocation of resources of trained clinicians.¹² ¹³

Over the last two decades, several systematic reviews have compared VC to IP.¹⁴⁻²⁰ These systematic reviews indicate that VC for outpatients in psychiatry is equivalent to IP consultations regarding effectiveness (psychopathology, patient satisfaction, and working alliance). Unfortunately, the majority of these reviews have been descriptive in nature and they have included studies of varying quality. Currently, there is a lack of quantitative analyses to determine the efficacy of VC compared to IP treatment.

Two meta-analyses conducted by Drago (2016) and Batastini (2021) have examined outcomes comparing VC to IP treatment.^{21 22} Drago et al. examined general interventions within psychiatry but excluded psychotherapeutic interventions and found that VC was not inferior to IP across a range of mental health outcomes. Batastini et al. carried out a comprehensive comparison of VC and IP interventions within mental health and found no significant differences on outcomes between the two treatment formats. Batastini et al. included a range of study designs (randomized and non-randomized trials), different treatment formats (individual and group) across a broad range of mental health related outcomes (symptoms, hospitalization, relapse, medication compliance). Both research groups indicated that results from treatment using VC was comparable to IP treatment but they noted a number of limitations with their respective reviews and recommended that further trials and reviews were necessary. They particularly highlighted the need for rigorous study designs, analysis investigating different psychiatric disorders and causes of heterogeneity, and clearly defined interventions and diagnostic descriptions of participants to improve the evidence base comparing VC and IP interventions.

Satisfaction outcomes in studies comparing VC to IP in psychiatric outpatients have been assessed in a single meta-analysis by Hyler.²³ Hyler et al. concludes that there was no difference in patient satisfaction between VC and IP modalities, consistent with results from published systematic reviews. Nevertheless, Hyler et al. reports that only a few studies have attempted to compare VC with IP using standardized satisfaction instruments. Considerable numbers of the included studies in the meta-analysis applied ad hoc or untested satisfaction instruments, and thus reliability or validity were not reported for these instruments. It is essential to use standardized and empirically evaluated tools as the basis for meaningful comparisons between different studies, as stated by Attkisson.24

Working alliance has only been assessed in a single meta-analysis conducted by Norwood (2018), who concludes that VC was inferior to IP regarding the alliance.²⁵ This contrasts with the systematic reviews that suggest that alliance in individual VC is equal to or even better than IP consultation.^{15 18 20}

To our knowledge, no meta-analysis on the dropout rate in VC compared to IP has been conducted in the scientific literature- a gap we hope this review can fill.

Based on the current research examining interventions using VC compared to IP consultations, there is a need to conduct a meta-analysis covering a range of psychiatric disorders and focusing on multiple clinical outcomes. This meta-analysis will build upon previous research and address some of the current limitations in the literature by conducting a systematic review including studies with rigorous study design (only RCT's), defined clinical interventions (individual treatment), specific psychiatric populations (diagnoses of anxiety, depression or personality disorder) using standardized assessments for psychopathology, working alliance and treatment satisfaction.

The specific objective of this systematic review is to examine if individual psychiatric outpatient interventions for adults conducted using VC are comparable to IP in terms of (1) psychopathology outcomes, (2) levels of patient satisfaction, (3) working alliance, and (4) dropout from treatment.

METHODS AND ANALYSIS This protocol will be conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P).²⁶ The PISMA-P checklist can be found in the online supplemental file 1. The review has been registered in the PROSPERO International Prospective Register of Systematic Reviews (Registration number CRD42021256357)

Eligibility criteria will be based and restricted on the type of study, population, intervention, comparator, and outcomes of the studies.

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Types of studies

Randomized controlled trials.

Types of Participants

Participants are (1) adults (>18 years), (2) receiving individual psychiatric ambulant treatment, and (3) diagnosed with mood disorders, anxiety, or personality disorders according to both the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) III, IV and 5 and the WHO's International Statistical Classification of Diseases (ICD) 9 or 10. Participants with comorbid diagnoses will also be included apart from those diagnoses covered in the exclusion criteria

Types of intervention

Individual treatment through synchronous real-time VC in outpatient settings.

Types of comparator/control

Individual treatment IP and same active treatment as the intervention group receives.

Types of Outcomes

Eligible studies have assessed psychopathology following a mental health service. The secondary outcome of interest includes (a) patient satisfaction, (b) working alliance, (c) and dropout rate.

Exclusion criteria

- Non-RCT studies
- Participant < 18 years
- Group therapy
- Different psychotherapy (treatments) approaches in intervention and control group.
- Trials primarily assessing schizophrenic and psychotic disorders, mental retardation, bipolar disorders, alcohol abuse, and substance use disorders will be excluded.
- Trials using asynchronous communications systems as an intervention (E.g., mails and static website without VC function) and telephone (only audio) as the intervention will not be included.

Information sources and search strategy

The first step in the systematic review has been a comprehensive electronic databases search. The databases search strings were created in January 2021 by AS with guidance from the information specialist Trine Kæstel, who has expertise in systematic review searching (Psychiatric Research Unit, Region Zealand). The database search strategy was developed with input from the project team.

The databases used for the searches are as follow; Medline (Pubmed interface, 1986 onwards), APA PsycINFO (OVID interface, 1967 onwards), Embase (OVID interface, 1974 onwards), Web of Science (Clarivate interface, 2001 onwards), and CINAHL (EBSCOhost interface, 1981 onwards).

Medical subject headings (MeSH) and text words related to the search terms "psychiatry" and "video consultation" were used for developing the search string in MEDLINE. Both search terms- psychiatry and video consultation- were then combined with [AND]. Specific syntax and subject headings were subsequently adapted individually to the different databases.

No language and date restriction was implemented in the search process. Due to the unmanageable results (>20.000 hits) in the preliminary search, Cochrane's highly sensitive search strategy filters identifying randomized trials has been applied in the final search string. Repeated search will be performed prior to the final analysis to identify further eligible studies. Unpublished studies will not be sought.

The second step in the search strategy will be a manual literature search to identify additional primary studies for the systematic review.

The third step will be scanning the reference lists of included studies or relevant reviews identified in the first and second steps.

Data management Records from the literature search will be exported to the reference manager Endnote X9.²⁷ From Endnote records will be exported to Covidence. Covidence is a web-application tool that facilitates collaboration among the review team members during the study selection and data extraction process.²⁸ Extracted data in Covidence will be exported to RevMan 5.4 for data analysis.²⁹

Selection process AS and SA will be responsible for the selection process. In the first step, the two authors will independently screen the title and abstracts of the records in Covidence to identify potentially eligible records. The Second step will be obtaining and screening full-text reports to decide if reports meet eligible criteria. Disagreement through the selection process will be resolved by discussion between the two authors. In case of continued disagreement despite discussion, a third reviewer (OJ) will be consulted. The selection process- including exclusion reasons- will be documented in the PRISMA-P flow diagram.

Data collection process AS and SA will be responsible for the data collection process. Data extraction will be carried out through a standardized electronic data extraction form in Covidence that the two authors mentioned above will develop. The data extraction form will initially be piloted on some reports, and the

reviewers will meet and discuss the form before starting the review. Disagreement through the data collection process will be resolved by discussion between the two authors. In case of continued disagreement despite discussion, a third reviewer (OJ) will be consulted. If we encounter multiple reports of the same study, we will extract data from all reports into a single data collection form in Covidence.³⁰ Missing data will be obtained by contacting and requesting these data from the study authors.

Data items We will extract the following data items for each study: (a) study characteristics (authors, author contact details, aim of the study, trial design, location, trial size, sample size calculation, year of publication and country), (b) population characteristics (remote /rural area or urban, country, diagnosis/condition, comorbidity, mean age and gender) (c) intervention/control (internet connection speed, bandwidth, therapy type, number of consultation sessions and duration of consultation), (d) clinical outcome (assessments tool, psychopathology, satisfaction, alliance, and dropout rate). When reported in the studies, we will collect data from the "intention to treat" analysis; otherwise, per-protocol data will be collected. For crossover RCTs, only data before crossover will be used to prevent carryover effects and units of analysis errors.

Outcomes and prioritization The primary outcome in this review are psychopathology assessed by clinician or patient-rated scales. As we expect that different assessments tools have been used for measuring the primary outcome, we will priorities clinician rated scales and secondary patient-rated scales.

The secondary outcomes in the review will be (a) satisfaction, (b) working alliance, and (c) dropout rate. Satisfaction must be assessed by client satisfaction questionnaire-8 (CSQ-8)²⁴, and the working alliance must be assessed by the client working alliance inventory (WAI)³¹ in the included studies. The dropout rate is defined as the number of participants not completing scheduled treatment course.

Risk of bias in individual studies AS and SA will perform the risk of bias (quality) assessment in the individual studies. The revised Cochrane risk-of-bias tool for randomized trials (RoB 2)³⁰ will be applied. Our primary outcome –psychopathology- will be assessed for risk of bias in each study. The bias domain that will be assessed include (a) bias arising from the randomization process, (b) bias due to deviations from intended interventions, (c) bias due to missing outcome data, (d) bias in the measurement of the outcome, and (e) bias in the selection of the reported result. Overall risks of bias for each study outcome will be marked as: (1) "low risk of bias" if all domains are judged to be low, (2) "some concerns" if at least one domain are judged to raise some concerns but not to be at high risk of bias for any domain and (3) "high risk of bias" if any domain is judged to be at high risk of bias. Disagreement between the mentioned researchers regarding the risk of bias will be resolved through consensus or a third researcher (OJ). Covidence tool will be used to assess the risk of bias.

Data synthesis The general strategy for our data synthesis is to perform a quantitative synthesis (metaanalysis). A narrative synthesis will be performed if heterogeneity (I²) is substantially high and will include summary tables and descriptions of the findings. I² values will be judged as follows: 0% to 40% may represent little heterogeneity, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, and 75% to 100% represent considerable heterogeneity. Heterogeneity which is the percentage of variation across studies that is due to heterogeneity rather than chance will be grouped in (1) clinical, (2) methodological, and (3) statistical heterogeneity.³⁰ Clinical heterogeneity refers to the variation across studies regarding age, sex, diagnosis, treatment-site, and intervention characteristics (duration of VC, number of VC sessions, and time interval between VC sessions). Methodological heterogeneity refers to the variability in the risk of bias and outcome measurement tools. Statistical heterogeneity refers to the differences in the intervention effects of each trial being evaluated.

Quantitative synthesis

We will use the inverse-variance method for carrying out the meta-analysis. Larger studies with less variance will be given more weight in the meta-analysis due to more precise effect size estimates than smaller studies.

As we expect clinical and methodological heterogeneity in the pooled studies, we will use the random-effects model to obtain the overall effect size estimate. When heterogeneity is low a fixed-effect model will be chosen.

Continuous outcome measures

We will calculate the standardized mean difference (SMD) effect size for the primary outcome using Hedges' g formula. Because we intend to use different assessments tools to calculate the effect size for the primary outcome in each study, SMD will be statistically suitable for this. Forest plot will be used for presenting effect sizes and overall effect size. A 95% confidence interval will supplement the calculated effect sizes. Furthermore, we will calculate the I² statistic to quantify heterogeneity and Chi² statistic (χ^2) to test for heterogeneity (p \leq 0.1 significance level).

For the secondary outcomes- satisfaction and working alliance- we will calculate mean difference effect size (MD) as we have restricted these secondary outcomes to be assessed by a standardized tool (CSQ-8 and WAI). Therefore, standardizing is not needed to calculate the effect size across the studies. Beyond this, the same statistical approach for the primary outcome already described will be applied to the secondary outcomes satisfaction and working alliance.

We intend to combine"end of treatment" scores (post-intervention) and "change score" data (changes from baseline) to calculate the estimated overall effect size for both primary and secondary outcomes. This is a valid approach.³² If the change score is not reported or cannot be calculated, post-intervention data will be used as the second choice.

Dichotomous outcome measures

We will calculate the risk ratio (RR) effect size and its 95% confidence interval for the secondary outcome dropout rate. Forest plot will be used to present effect sizes and overall effect size and supplemented with I² and χ^2 statistics. We define dropout as the number of participants not completing scheduled treatment courses, i.e., the difference in the number of participants who started the first treatment session (baseline) and completed the treatment course (posttreatment).

Additional primary outcome analyses (investigating heterogeneity)

For the primary outcome, a subgroup analysis (a) for different patient groups will be performed based on participant diagnosis as specified in the eligibility criteria, (b) sex, (c) ages, (d) length of treatment course/program, (e) therapy type and (f) settings (remote /rural area or urban).

A sensitivity analysis will be performed to determine the robustness of the meta-analysis and will include:

1) removing low-quality studies and repeating the meta-analysis

2) testing for any possible difference between "end-of-treatment" scores and "change scores."

3) testing for whether the findings are sensitive to random-effects or fixed-effects models.

4) assessing the effect of the year of publication; a meta-regression will be performed, and a p-value for the regression will be calculated ($p \le 0.05$ significance level). The rationality for this meta-regression is to analyze if the technological or therapeutic evolution affects the primary outcome.

Meta-bias Publication bias will be assessed and will be done by visually assessing a funnel plot supplied by Egger's test.^{33 30}

Confidence in cumulative evidence We will use the GRADE approach (Grading of Recommendations Assessment, Development, and Evaluation) as recommended by Cochrane Collaboration to assess the confidence of the body of evidence.³⁰

Patient and Public Involvement No patient involved.

Ethics and dissemination No ethical approval is required for this systematic review protocol. The findings of this study will be published in a peer-review scientific journal.

STATESMENTS

Contributorship AS is the guarantor of the protocol and wrote the first draft protocol.

ES, SA, AS: developed the idea and rationale for the systematic review

OJS: Developed the idea for the protocol and provided statistical inputs

JAAS: Provided technological perspective and insight.

All authors revised and approved the final manuscript.

Competing interests None declared

Funding Psychiatric Research unit in Region Zealand, Denmark are funding this review protocol.

Data sharing We will deposit data sets in the Zenodo repository.

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Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

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Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

Reporting Item

Page

Number

49 50 51	Title			
52 53 54	Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
55 56 57	Update	<u>#1b</u>	If the protocol is for an update of a previous systematic	"n/a"
58			review, identify as such	
59 60		For peer	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3	Registration			
4 5		<u>#2</u>	If registered, provide the name of the registry (such as	1,2,4
6 7 8			PROSPERO) and registration number	
9 10 11 12	Authors			
13 14	Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all	1
15 16			protocol authors; provide physical mailing address of	
17 18 19			corresponding author	
20 21	Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the	8
22 23			guarantor of the review	
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29 30		<u>#4</u>	If the protocol represents an amendment of a previously	1
31 32			completed or published protocol, identify as such and list	
33 34			changes; otherwise, state plan for documenting important	
35 36			protocol amendments	
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39 40	Support			
41 42 43 44	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	8
45 46 47	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	8
48 49	Role of sponsor or	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or	8
50 51	funder		institution(s), if any, in developing the protocol	
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1 2 3	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is	2,3,4
4 5			already known	
6 7	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review	2,4
8 9 10			will address with reference to participants, interventions,	
11 12			comparators, and outcomes (PICO)	
13 14	Methods			
15 16				
17 18 10	Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study	4,5
19 20 21			design, setting, time frame) and report characteristics (such	
22 23			as years considered, language, publication status) to be	
24 25			used as criteria for eligibility for the review	
26 27				_
28	Information	<u>#9</u>	Describe all intended information sources (such as	5
29 30 31	sources		electronic databases, contact with study authors, trial	
32 33			registers or other grey literature sources) with planned dates	
34 35 36			of coverage	
30 37 38	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one	5
39 40			electronic database, including planned limits, such that it	
41 42 43			could be repeated	
44 45	Study records -	<u>#11a</u>	Describe the mechanism(s) that will be used to manage	5
46 47 48	data management		records and data throughout the review	
49 50 51	Study records -	<u>#11b</u>	State the process that will be used for selecting studies	5
52 53	selection process		(such as two independent reviewers) through each phase of	
54 55			the review (that is, screening, eligibility and inclusion in	
56 57 58			meta-analysis)	
58 59 60		For peer	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Study records -	<u>#11c</u>	Describe planned method of extracting data from reports	5,6
3 4	data collection		(such as piloting forms, done independently, in duplicate),	
5 6 7	process		any processes for obtaining and confirming data from	
7 8 9			investigators	
10 11 12	Data items	<u>#12</u>	List and define all variables for which data will be sought	6
13 14			(such as PICO items, funding sources), any pre-planned	
15 16 17			data assumptions and simplifications	
18 19 20	Outcomes and	<u>#13</u>	List and define all outcomes for which data will be sought,	6
20 21 22	prioritization		including prioritization of main and additional outcomes, with	
23 24 25			rationale	
26 27	Risk of bias in	<u>#14</u>	Describe anticipated methods for assessing risk of bias of	6
28 29 20	individual studies		individual studies, including whether this will be done at the	
30 31 32			outcome or study level, or both; state how this information	
33 34			will be used in data synthesis	
35 36 37	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be	6
38 39 40			quantitatively synthesised	
41 42 43	Data synthesis	<u>#15b</u>	If data are appropriate for quantitative synthesis, describe	6,7
44 45			planned summary measures, methods of handling data and	
46 47			methods of combining data from studies, including any	
48 49 50			planned exploration of consistency (such as I2, Kendall's τ)	
51 52	Data synthesis	<u>#15c</u>	Describe any proposed additional analyses (such as	7
53 54 55			sensitivity or subgroup analyses, meta-regression)	
56 57 58				
59 60		For peer	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type	6
3 4 5			of summary planned	
6 7 8	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as	7
9 10			publication bias across studies, selective reporting within	
11 12 13			studies)	
14 15	Confidence in	<u>#17</u>	Describe how the strength of the body of evidence will be	8
16 17	cumulative		assessed (such as GRADE)	
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BMJ Open

Treatment effect of individual video consultation vs inperson consultation in mood, anxiety and personality disorders: a protocol for a systematic review and metaanalysis

Journal:	BMJ Open
Manuscript ID	bmjopen-2021-060690.R1
Article Type:	Protocol
Date Submitted by the Author:	27-May-2022
Complete List of Authors:	Shaker, Ali; Psychiatric Services Region Zealand, Psychiatric Research Unit; University of Copenhagen, Department of Clinical Medicine Austin, Stephen; Psychiatric Services Region Zealand, Psychiatric Research Unit Slagelse Sørensen, John; Technical University of Denmark, Engineering Technology Storebø, Ole Jakob; Psychiatric Services Region Zealand, Psychiatric Research Unit Simonsen, Erik; Psychiatric Services Region Zealand, Psychiatric Reseach unit; University of Copenhagen, Clinical Medicine
Primary Subject Heading :	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, PSYCHIATRY, Information technology < BIOTECHNOLOGY & BIOINFORMATICS, Adult psychiatry < PSYCHIATRY, COVID-19

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ADMINISTRATIVE INFORMATION

Title Treatment effect of individual video consultation *vs* in-person consultation in mood, anxiety and personality disorders: a protocol for a systematic review and meta-analysis

Registration This protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 2 July 2021 (Registration number CRD42021256357)

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Amendments Any deviation from the initial protocol during the review process will be documented in PROSPERO registry and reported in the final report.

Word Count 3100

ABSTRACT

Introduction Major advancements in technology has led to considerations how video consultation (VC) and other technology platforms can be meaningfully integrated in treatment for psychiatric disorders. The COVID-19 pandemic has placed a further focus on use of VC in psychiatry. Despite the widespread use of VC, little is known about its effect compared to traditional in-person (IP) consultation. The objective of this systematic review is to examine if individual psychiatric outpatient interventions for adults using VC are comparable to IP in terms of (1) psychopathology outcomes, (2) levels of patient satisfaction, (3) working alliance, and (4) dropout from treatment.

Methods and analysis This review will only include randomized controlled trials for adult participants with mood disorders, anxiety, or personality disorders. The primary outcome is psychopathology, and secondary outcomes include patient satisfaction, treatment alliance, and dropout rate. Systematic searches were conducted in MEDLINE, APA PsycINFO, Embase, Web of Science, and CINAHL. The inverse-variance method will be used to conduct the meta-analysis. Effect sizes will be calculated as standardized mean difference (Hedges' g) for the primary outcome, mean difference (MD) for patient satisfaction and working alliance, and risk ratio (RR) for the dropout rate. Effect sizes will be supplemented with 95% CI. We will calculate the I² statistic to quantify heterogeneity and Chi2 statistic (χ^2) to test for heterogeneity for the primary outcome. Potential clinical and methodological heterogeneity moderators will be assessed in subgroup and sensitivity analysis. The risk of bias will be assessed by Cochrane Risk of Bias Tool 2, and confidence in cumulative evidence will be assessed by GRADE.

Ethics and dissemination No ethical approval is required for this systematic review protocol. The findings of this study will be published in a peer-review scientific journal.

PROSPERO registration number CRD42021256357 Y.C.

Article summary

Strengths and limitations of this study

- This review will include randomized controlled trials to compare individual psychiatric treatment • using VC or IP for people with mood, anxiety, or personality disorders.
- Validated and standardized measures will be used to assess psychopathology, patient satisfaction • (CSQ-8) and working alliance (WAI) across all the studies.
- This systematic review will calculate and compare dropout rates between VC and IP treatment • formats. An outcome that has not previously been examined in a systematic review.
- The stringent eligibility criteria regarding study design, participants, interventions and outcome • measures will result in some studies being excluded.

INTRODUCTION

Video consultation (VC) is a virtual consultation where the communication is synchronous (occurs in real-time) while the patient and clinician are in different physical locations. Various names have been suggested and used interchangeably in the scientific literature to describe VC. Telehealth, telepsychiatry, telemental health, and teleconsultation, for example, are commonly used. Telemedicine (healing at a distance) is the broader term and covers synchronous (Video, Telephone) and asynchronous ("Store and forward," i.e., Emails, SMS) technologies. ^{1 2} Telepsychiatry is a specific type of telemedicine used in the psychological and psychiatric fields. ³ A specific type of synchronous telepsychiatry technology includes VC which is the focus of this paper.

Experimentation with VC in medical settings first began in the 1950s. These studies were based on a simple two-way closed-circuit television and VC was used for treatment and education purposes.⁴ Advances in technology and increasing access to the internet mean that VC can now be quickly accessed using a smartphone or other digital devices.^{5 6 7} Furthermore, the COVID-19 pandemic has led to the accelerated use of digital solutions in health care systems in many countries.^{8 9 10} Currently, there a number of large ongoing trials comparing VC to IP in populations of depression, anxiety and perinatal women. ^{11 12 13}

The use of VC in mental health services has several potential advantages such as making psychiatric services more accessible and flexible, reducing the cost of transport and time, reducing stigma, promoting patient autonomy, and providing an opportunity for people with mental health difficulties to engage with services if they find it challenging to attend in-person (IP) consultations.^{14 15}

There are also some potential disadvantages of VC, which include concerns about data security, technical obstacles, questions regarding the efficacy of interventions grounded in VC, which patient groups VC is most suitable for, concerns about establishing good working alliances, maintaining treatment engagement, and the allocation of resources of trained clinicians.^{16 17} Different populations (eg: geriatric, suicidal or perinatal) can also experience a range of barriers and challenges using VC such as issues of privacy and safety, difficulty learning new technologies or the provision of care for acute mental health problems.^{11 18 19}

Over the last two decades, several systematic reviews have compared VC to IP within psychiatry.²⁰⁻²¹ These systematic reviews indicate that VC for psychiatric outpatients is equivalent to IP consultations regarding effectiveness (psychopathology, patient satisfaction, and working alliance). Unfortunately, the majority of these reviews have usually been descriptive in nature and included studies of varying quality. Currently, there is a lack of quantitative analyses to determine the efficacy of psychiatric treatment provided by VC compared to IP formats.

Three meta-analyses conducted by Drago (2016), Batastini (2021), and Giovanetti (2022) have examined outcomes comparing VC to IP treatment.^{22 23 24} Drago et al. examined a wide range of interventions within psychiatry but excluded psychotherapeutic interventions. They found that VC was not inferior to IP across a range of mental health outcomes. Batastini et al. carried out a large review of VC and IP for a broad range of psychotherapeutic interventions within mental health and they found no significant differences in outcomes between the two treatment formats. Batastini et al. review included a range of study designs (randomized and non-randomized trials) and different treatment formats (individual and group) across a broad range of mental health related outcomes (symptoms, hospitalization, relapse, medication compliance). Giovanetti et al. conducted a systematic review and meta-analysis to examine the treatment effect for patients with depressive symptoms. Their meta-analysis included 11 RCT studies that directly compared individual psychotherapy through VC with IP and they found no significant differences in outcomes between the two treatment formats. Results from the three reviews conducted indicate that treatment using VC is comparable to IP treatment, although the three research groups also acknowledge a number of limitations with their respective reviews. They recommend that further trials and reviews were necessary and highlight the need for more

rigorous study designs, inclusion of a broader range of psychiatric disorders, clearly defined interventions and detailed diagnostic descriptions to develop the evidence base when comparing VC and IP interventions.

Satisfaction outcomes in studies comparing VC to IP in psychiatric outpatients have been assessed in a single meta-analysis by Hyler.²⁵ This review concluded that there were no differences in levels of patient satisfaction between VC and IP modalities although the authors noted that only a few studies used standardized satisfaction instruments. A number of studies applied ad hoc or untested satisfaction instruments, where the reliability or validity was not reported. It is essential to use standardized and empirically evaluated measures to allow meaningful comparisons between different studies.²⁶

Working alliance was assessed in meta-analysis conducted by Norwood (2018), that concluded that alliance in VC treatment was inferior to IP treatment.²⁷ This finding contrasts with other systematic reviews that suggest that alliance in individual treatment using VC was equal or better than IP treatment.²⁸ ²⁹ ²¹

Currently, there is no meta-analysis on dropout rates in treatment using VC compared and IP making it a research area that needs to be addressed.

Based on the current research examining interventions using VC compared to IP consultations, there is a need to conduct a meta-analysis covering a range of psychiatric disorders and focusing on multiple clinical outcomes. This meta-analysis will build upon previous research and address some of the current limitations in the literature by conducting a systematic review including studies with rigorous study design (only RCT's), defined clinical interventions (individual treatment), specific psychiatric populations (diagnoses of anxiety, depression or personality disorder) using standardized assessments for psychopathology, working alliance and treatment satisfaction.

The specific objective of this systematic review is to examine if individual psychiatric outpatient interventions for adults conducted using VC are comparable to IP in terms of (1) psychopathology outcomes, (2) levels of patient satisfaction, (3) working alliance, and (4) dropout from treatment.

METHODS AND ANALYSIS This protocol will be conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P).³⁰ The PRISMA-P checklist can be found in the online supplemental file 1. The review has been registered in the PROSPERO International Prospective Register of Systematic Reviews (Registration number CRD42021256357). The anticipated start date is August 2022. The anticipated end date is February 2023.

Eligibility criteria will be based and restricted on the type of study, population, intervention, comparator, and outcomes of the studies.

Types of studies

Randomized controlled trials.

Types of Participants

Participants are (1) adults (>18 years), (2) receiving individual psychiatric ambulant treatment, and (3) diagnosed with mood disorders, anxiety, or personality disorders according to both the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) III, IV and 5 and the WHO's International Statistical Classification of Diseases (ICD) 9 or 10. Participants with comorbid diagnoses will also be included apart from those diagnoses covered in the exclusion criteria

Types of intervention

Individual treatment through synchronous real-time VC in outpatient settings. Treatment is defined as intervention involving psychotherapy, pharmacological treatment or psychoeducation.

 Individual treatment IP and same active treatment as the intervention group receives.

Types of Outcomes

Eligible studies have assessed psychopathology following a mental health service. The secondary outcome of interest includes (a) patient satisfaction, (b) working alliance, (c) and dropout rate.

Exclusion criteria

- Non-RCT studies
- Participant < 18 years
- Group therapy
- Different psychotherapy (treatments) approaches in intervention and control group.
- Trials involving populations that primarily treating psychotic disorders, mental retardation, bipolar disorders, alcohol abuse, and substance use disorders will be excluded.
- Trials using asynchronous communications systems as an intervention (E.g., mails and static website without VC function) and telephone (only audio) as the intervention will not be included.

Information sources and search strategy

The first step in the systematic review has been a comprehensive search in electronic databases. The database search strings were created in January 2021 by AS with guidance from the information specialist Trine Kæstel, who has expertise in systematic review searching (Psychiatric Research Unit, Region Zealand). The database search strategy was developed with input from the project team. Search strategies are provided in the supplementary file 2.

The databases used for the searches are as follow; Medline (Pubmed interface, 1986 onwards), APA PsycINFO (OVID interface, 1967 onwards), Embase (OVID interface, 1974 onwards), Web of Science (Clarivate interface, 2001 onwards), and CINAHL (EBSCOhost interface, 1981 onwards).

Medical subject headings (MeSH) and text words related to the search terms "psychiatry" and "video consultation" were used for developing the search string in MEDLINE. Both search terms- psychiatry and video consultation- were then combined with [AND]. Specific syntax and subject headings were subsequently adapted individually to the different databases.

No language and date restriction was implemented in the search process. Due to the unmanageable results (>20.000 hits) in the preliminary search, Cochrane's highly sensitive search strategy filters identifying randomized trials has been applied in the final search string. Repeated search will be performed prior to the final analysis to identify further eligible studies. Unpublished studies will not be sought.

The second step in the search strategy will be a manual literature search to identify additional primary studies for the systematic review.

The third step will be scanning the reference lists of included studies or relevant reviews identified in the first and second steps.

Data management Records from the literature search will be exported to the reference manager Endnote X9.³¹ From Endnote records will be exported to Covidence. Covidence is a web-application tool that

facilitates collaboration among the review team members during the study selection and data extraction process.³² Extracted data in Covidence will be exported to RevMan 5.4 for data analysis.³³

Selection process AS and SA will be responsible for the selection process. In the first step, the two authors will independently screen the title and abstracts of the records in Covidence to identify potentially eligible records. The Second step will be obtaining and screening full-text reports to decide if reports meet eligible criteria. Disagreement through the selection process will be resolved by discussion between the two authors. In case of continued disagreement despite discussion, a third reviewer, OJS will be consulted. The selection process- including exclusion reasons- will be documented in the PRISMA-P flow diagram. Inter-rater reliability will be measured by Cohen's kappa coefficient (κ) for the (1) title and abstract screening process and (2) full-text review process.

Data collection process AS and SFA will be responsible for the data collection process. Data extraction will be carried out through a standardized electronic data extraction form in Covidence. The data extraction form will initially be piloted on some reports, and the reviewers will meet and discuss the form before starting the review. Disagreement through the data collection process will be resolved by discussion between the two authors. In case of continued disagreement despite discussion, a third reviewer (OJS) will be consulted. If we encounter multiple reports of the same study, we will extract data from all reports into a single data collection form in Covidence.³⁴ Missing data will be obtained by contacting and requesting these data from the study authors.

Data items We will extract the following data items for each study: (a) study characteristics (authors, author contact details, aim of the study, trial design, location, trial size, sample size calculation, year of publication and country), (b) population characteristics (remote /rural area or urban, country, diagnosis/condition, comorbidity, mean age and gender) (c) intervention/control (internet connection speed, bandwidth, therapy type, number of consultation sessions and duration of consultation), (d) clinical outcome (assessments tool, psychopathology, satisfaction, alliance, and dropout rate). When reported in the studies, we will collect data from the "intention to treat" analysis; otherwise, per-protocol data will be collected. For crossover RCTs, only data before crossover will be used to prevent carryover effects and units of analysis errors.

Outcomes and prioritization The primary outcome in this review is psychopathology assessed by clinician or patient-rated scales. As we expect that different assessments tools have been used for measuring the primary outcome, we will priorities clinician rated scales and secondary patient-rated scales.

The secondary outcomes in the review will be (a) patient satisfaction, (b) working alliance, and (c) dropout rate. Satisfaction must be assessed by client satisfaction questionnaire-8 (CSQ-8)²⁶, and the working alliance must be assessed by the client working alliance inventory (WAI)³⁵ in the included studies. The dropout rate is defined as the number of participants not completing scheduled treatment course.

Risk of bias in individual studies AS and SFA will perform the risk of bias (quality) assessment in the individual studies. The revised Cochrane risk-of-bias tool for randomized trials (RoB 2)³⁴ will be applied. Our primary outcome –psychopathology- will be assessed for risk of bias in each study. The bias domain that will be assessed include (a) bias arising from the randomization process, (b) bias due to deviations from intended interventions, (c) bias due to missing outcome data, (d) bias in the measurement of the outcome, and (e) bias in the selection of the reported result. Overall risks of bias for each study outcome will be marked as: (1) "low risk of bias" if all domains are judged to be low, (2) "some concerns" if at least one domain are judged to raise some concerns but not to be at high risk of bias for any domain and (3) "high risk of bias" if any domain is judged to be at high risk of bias. Disagreement between the mentioned researchers regarding the risk of bias will be resolved through consensus or a third researcher (OJS). Covidence tool will be used to assess the risk of bias.

Data synthesis The general strategy for our data synthesis is to perform a quantitative synthesis (metaanalysis). A narrative synthesis will be performed if heterogeneity (I²) is substantially high and will include summary tables and descriptions of the findings. I² values will be judged as follows: 0% to 40% may represent little heterogeneity, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, and 75% to 100% represent considerable heterogeneity. Heterogeneity which is the percentage of variation across studies that is due to heterogeneity rather than chance will be grouped in (1) clinical, (2) methodological, and (3) statistical heterogeneity.³⁴ Clinical heterogeneity refers to the variation across studies regarding age, sex, diagnosis, treatment-site, and intervention characteristics (duration of VC, number of VC sessions, and time interval between VC sessions). Methodological heterogeneity refers to the variability in the risk of bias and outcome measurement tools. Statistical heterogeneity refers to the differences in the intervention effects of each trial being evaluated.

Quantitative synthesis

We will use the inverse-variance method for carrying out the meta-analysis. Larger studies with less variance will be given more weight in the meta-analysis due to more precise effect size estimates than smaller studies. As we expect clinical and methodological heterogeneity in the pooled studies, we will use the random-effects model to obtain the overall effect size estimate. When heterogeneity is low a fixed-effect model will be chosen.

Continuous outcome measures

We will calculate the standardized mean difference (SMD) effect size for the primary outcome using Hedges' g formula. Because we intend to use different assessments tools to calculate the effect size for the primary outcome in each study, SMD will be statistically suitable for this. Forest plot will be used for presenting effect sizes and overall effect size. A 95% confidence interval will supplement the calculated effect sizes. Furthermore, we will calculate the I² statistic to quantify heterogeneity and Chi² statistic (χ^2) to test for heterogeneity (p \leq 0.1 significance level).

For the secondary outcomes- satisfaction and working alliance- we will calculate mean difference effect size (MD) as we have restricted these secondary outcomes to be assessed by a standardized tool (CSQ-8 and WAI). Therefore, standardizing is not needed to calculate the effect size across the studies. Beyond this, the same statistical approach for the primary outcome already described will be applied to the secondary outcomes satisfaction and working alliance.

We intend to combine"end of treatment" scores (post-intervention) and "change score" data (changes from baseline) to calculate the estimated overall effect size for both primary and secondary outcomes. This is a valid approach.³⁶ If the change score is not reported or cannot be calculated, post-intervention data will be used as the second choice.

Dichotomous outcome measures

We will calculate the risk ratio (RR) effect size and its 95% confidence interval for the secondary outcome dropout rate. Forest plot will be used to present effect sizes and overall effect size and supplemented with I² and χ^2 statistics. We define dropout as the number of participants not completing scheduled treatment courses, i.e., the difference in the number of participants who started the first treatment session (baseline) and completed the treatment course (posttreatment).

Additional primary outcome analyses (investigating heterogeneity)

For the primary outcome, a subgroup analysis (a) for different patient groups will be performed based on participant diagnosis as specified in the eligibility criteria, (b) sex, (c) ages, (d) length of treatment course/program, (e) therapy type and (f) settings (remote /rural area or urban).

A sensitivity analysis will be performed to determine the robustness of the meta-analysis and will include:

1) removing low-quality studies and repeating the meta-analysis

2) testing for any possible difference between "end-of-treatment" scores and "change scores."

3) testing for whether the findings are sensitive to random-effects or fixed-effects models.

4) assessing the effect of the year of publication; a meta-regression will be performed, and a p-value for the regression will be calculated ($p \le 0.05$ significance level). The rationality for this meta-regression is to analyze if the technological or therapeutic evolution affects the primary outcome.

Meta-bias Publication bias will be assessed and will be done by visually assessing a funnel plot supplied by Egger's test.^{37 34}

Confidence in cumulative evidence We will use the GRADE approach (Grading of Recommendations Assessment, Development, and Evaluation) as recommended by Cochrane Collaboration to assess the confidence of the body of evidence.³⁴

Patient and Public Involvement No patients are involved.

Ethics and dissemination No ethical approval is required for this systematic review protocol. The findings of this study will be published in a peer-review scientific journal.

STATEMENTS

Contributors AS is the guarantor of the protocol and wrote the first draft protocol.

ES, SFA, AS: developed the idea and rationale for the systematic review

OJS: Developed the idea for the protocol and provided statistical inputs

JAAS: Provided technological perspective and insight.

All authors revised and approved the final manuscript.

Competing interests None declared

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Data sharing We will deposit data sets in the Zenodo repository.

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3 4 37. 5	Egger M, Smith GD, Schneider M, Minder C. Papers Bias in Meta-Analysis Detected by a Simple, Graphical Test.
6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 5 7 8 9 0 1 1 2 3 8 9 0 1 1 2 3 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 1 2 8 9 0 1 8 9 0 1 1 2 8 9 0 1 1 8 9 0 1 1 8 9 0 1 1 8 9 0 1 1 8 9 0 1 1 8 9 0 1 1 8 9 0 1 8 9 0 1 1 2 8 9 0 1 8 9 0 1 1 8 9 0 1 8 8 9 0 1 8 9 0 1 8 8 8 9 1 8 9 9 0 1 8 8 8 9 1 8 8 9 1 8 8 8 8 9 1 8 8 9 8 8 8 8	Egger M, Smith GD, Schneider M, Minder C. Papers Bias in Meta-Analysis Detected by a Simple. Graphical Test.

Appendix 2- Search Strategies

#	Searches
1	exp Treatment Effectiveness Evaluation/
2	exp Treatment Outcomes/
3	exp Placebo/
4	exp Followup Studies/
5	placebo*.mp.
6	random*.mp.
7	comparative stud*.mp.
8	(clinical adj3 trial*).mp.
9	(research adj3 design).mp.
10	(evaluat* adj3 stud*).mp.
11	(clinical adj3 trial*).mp.
12	(research adj3 design).mp.
13	(evaluat* adj3 stud*).mp.
14	(prospectiv* adj3 stud*).mp.
15	((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*)).mp.
16	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17	exp Psychiatry/
18	exp Mental Health/
19	exp Mental Disorders/
20	exp Mental Health Services/
21	mental health counseling.ab,sh,ti,tw.
22	mental health consultation.ab,sh,ti,tw.
23	psychiatric consultation.ab,sh,ti,tw.
24	psychiatric day treatment.ab,sh,ti,tw.
25	mental health care.ab,sh,ti,tw.
26	psychiatric home care.ab,sh,ti,tw.
27	"psychiatric outpatien*".ab,sh,ti,tw.
28	17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
29	exp Telemedicine/
30	exp Telepsychiatry/
31	exp Videoconferencing/
32	ehealth.ab,sh,ti,tw.
33	telecommunication.ab,sh,ti,tw.
34	telehealth.ab,sh,ti,tw.
35	telemental.ab,sh,ti,tw.
36	"telepsychiatr*".ab,sh,ti,tw.
37	"teletherap*".ab,sh,ti,tw.
38	"videoconferenc*".ab,sh,ti,tw.
39	videophone.ab,sh,ti,tw.
40	29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
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#	Searches
1	psychiatry/ or cultural psychiatry/ or emergency psychiatry/ or forensic psychiatry/ or gerontopsychiatry/ or
	liaison psychiatry/ or neuropsychiatry/ or psychosomatics/ or social psychiatry/ or telepsychiatry/
2	exp mental health/
3	mental disease/ or addiction/ or adjustment disorder/ or anxiety disorder/ or autism/ or behavior disorder/ or dissociative disorder/ or emotional disorder/ or mood disorder/ or neurosis/ or personality disorder/ or psychosis/ or schizophrenia spectrum disorder/
4	exp mental health service/
5	home mental health care/
6	"psychiatric consultation*".ab,kw,ti,tw.
7	mental health counseling.ab,kw,ti,tw.
8	psychiatric day treatment.ab,kw,ti,tw.
9	mental health care.ab,kw,ti,tw.
10	psychiatric home care.ab,kw,ti,tw.
11	psychiatric outpatient.ab,kw,ti,tw.
12	"psychiatric outpatient*".ab,kw,ti,tw.
13	mental health home care.ab,ao,kw,ti,tw.
14	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	telepsychiatry/
16	teleconsultation/ or telediagnosis/ or telemonitoring/ or telepathology/ or telepsychiatry/ or teleradiotherapy/ or telerehabilitation/ or teletherapy/
17	telehealth/
18	telecommunication/ or telemedicine/ or teleconsultation/ or telediagnosis/ or telepsychiatry/ or telerehabilitation/ or teletherapy/
19	videoconferencing/
20	"videoconferenc*".ab,ao,kw,ti,tw.
21	videophone.ab,ao,kw,ti,tw.
22	telehealth.ab,ao,kw,ti,tw.
23	telemental.ab,ao,kw,ti,tw.
24	ehealth.ab,ao,kw,ti,tw.
25	"teletherap*".ab,ao,kw,ti,tw.
26	telecommunication.ab,ao,kw,ti,tw.
27	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28	14 and 27
	(Randomized controlled trial/ or Controlled clinical study/ or random\$.ti,ab. or randomization/ or intermethod comparison/ or placebo.ti,ab. or (compare or compared or comparison).ti. or ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. or (open adj label).ti,ab. or ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. or double blind procedure/ or parallel group\$1.ti,ab. or (crossover or cross over).ti,ab. or ((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant\$1)).ti,ab. or (assigned or allocated).ti,ab. or (controlled adj7 (study or design or trial)).ti,ab. or (volunteer or volunteers).ti,ab. or human experiment/ or trial.ti.) not (((random\$ adj sampl\$ adj7 ("cross section\$" or questionnaire\$1 or survey\$ or database\$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or controlled study/ or controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or ((case adj control\$) and random\$) not randomi?ed controlled.ti,ab. or (random cluster adj3 sampl\$).ti,ab. or ((review.ab. and review.pt.) not trial.ti.) or ("we searched".ab. and (review.ti. or review.pt.)) or "update review".ab. or (databases adj4 searched).ab. or ((rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset\$1).ti. and animal experiment/) or (Anima
30	experiment/ not (human experiment/ or human/))) 28 and 29

Search Strategy for: *Medline* Pubmed Interface

Query

((((((((trial [ti]) OR (randomly [tiab])) OR (clinical trials as topic [mesh: noexp])) OR (placebo [tiab])) OR (randomized [tiab])) OR (controlled clinical trial [pt])) OR (randomized controlled trial [pt])) NOT (animals [mh] NOT humans [mh]))

BMJ Open

AND (("Psychiatry"[MeSH Terms] OR "Mental Disorders"[MeSH Terms] OR "Mental Health Services"[MeSH Terms] OR "Mental Health"[MeSH Terms] OR ("mental health counseling"[Title/Abstract] OR "mental health consultation"[Title/Abstract] OR "psychiatric consultation*"[Title/Abstract] OR "psychiatric day treatment"[Title/Abstract] OR "mental health care"[Title/Abstract] OR "psychiatric outpatient*"[Title/Abstract] OR "community mental health"[Title/Abstract]))

AND ("Telemedicine"[MeSH Terms] OR "Videoconferencing"[MeSH Terms] OR "Remote Consultation"[MeSH Terms] OR ("ehealth"[Title/Abstract] OR "telecare"[Title/Abstract] OR "teleconsultation*"[Title/Abstract] OR "telehome"[Title/Abstract] OR "telemedic*"[Title/Abstract] OR "telepsychiatr*"[Title/Abstract] OR "telemental"[Title/Abstract] OR "televideo"[Title/Abstract] OR "videoconferenc*"[Title/Abstract] OR "videophone"[Title/Abstract] OR "telehealth"[Title/Abstract] OR "telemental"[Title/Abstract] OR "ehealth"[Title/Abstract] OR "telehealth"[Title/Abstract] OR "telemental"[Title/Abstract] OR "ehealth"[Title/Abstract] OR "video conferencing"[Title/Abstract] OR "telecommunication*"[Title/Abstract] OR "teletherapy"[Title/Abstract]))))

Sea	arch Strategy for: Web Of Science						
Cla	Clarivate interface						
#	Searches						
1	(Psychiatr* OR (mental NEAR (health OR disorder* OR ill*)) OR (counseling NEAR psychology) OR (mental NEAR (counseling OR						
	consultation*)) OR "psychiatric consultation*" OR "psychiatric day treatment" OR "psychiatric home care" OR "me ntal health service*")						
2	(e-health OR telecare OR teleconsultation* OR telehome OR telemedic* OR telepsych* OR telemental* OR televideo* OR videoconference* OR videophone OR telehealth OR ehealth OR "video conferencing" OR Telecommunication* OR teletherap* OR teleconference*)						
3	2 AND #1						
4	TS=(randomised OR randomized OR randomisation OR randomisation OR placebo* OR (random* AND (allocat* OR						
	assign*)) OR (blind* AND (single OR double OR treble OR triple)))						
5	#4 AND #3						

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	h Strategy for: <i>Cinahl</i>
	Cohost interface
#	Searches
S55	S31 AND S54 Expanders - Apply equivalent subjects
S54	S53 NOT S52 Expanders - Apply equivalent subjects
<i>S53</i>	S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 O
950	S46 Expanders - Apply equivalent subjects
S52	S50 NOT S51 Expanders - Apply equivalent subjects
<u>S51</u> S50	MH (human) Expanders - Apply equivalent subjects
S30 S49	S47 OR S48 OR S49 Expanders - Apply equivalent subjects
S49 S48	TI (animal model*) Expanders - Apply equivalent subjects MH (animal studies) Expanders - Apply equivalent subjects
S48 S47	MH (animal studies) Expanders - Apply equivalent subjects MH animals+ Expanders - Apply equivalent subjects
S47 S46	AB (cluster W3 RCT) Expanders - Apply equivalent subjects
S40 S45	<i>MH</i> (crossover design) <i>OR MH</i> (comparative studies) <i>Expanders</i> - Apply equivalent subjects
S43	
S44 S43	AB (control W5 group) Expanders - Apply equivalent subjects
	PT (randomized controlled trial) Expanders - Apply equivalent subjects
S42	MH (placebos) Expanders - Apply equivalent subjects
S41	MH (sample size) AND AB (assigned OR allocated OR control) Expanders -Apply equivalent subjects
S40	TI (trial) Expanders - Apply equivalent subjects
S39	AB (random*) Expanders - Apply equivalent subjects
<i>S38</i>	TI (randomised OR randomized) Expanders - Apply equivalent subjects
S37	MH cluster sample Expanders - Apply equivalent subjects
S36	MH pretest-posttest design Expanders - Apply equivalent subjects
S35	MH random assignment Expanders - Apply equivalent subjects
<i>S34</i>	MH single-blind studies Expanders - Apply equivalent subjects
<i>S33</i>	MH double-blind studies Expanders - Apply equivalent subjects
<i>S32</i>	MH randomized controlled trials Expanders - Apply equivalent subjects
<i>S31</i>	S29 AND S30 Expanders - Apply equivalent subjects
<i>S30</i>	S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 O
GO O	S26 OR S27 OR S28 Expanders - Apply equivalent subjects
S29	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 Expanders - Apply equivalent subject
S28	AB teleconference OR TI teleconference Expanders - Apply equivalent subjects
S27	AB teletherapy OR TI teletherapy Expanders - Apply equivalent subjects
S26	AB telemental health OR TI telemental health Expanders - Apply equivalent subjects
S25	AB videophone OR TI videophone Expanders - Apply equivalent subjects
S24	AB videoconference OR TI videoconference Expanders - Apply equivalent subjects
S23	AB televideo OR TI televideo Expanders - Apply equivalent subjects
S22	AB telemental OR TI telemental Expanders - Apply equivalent subjects
S21	AB telepsychiatric OR TI telepsychiatric Expanders - Apply equivalent subjects
S20	AB telemedical OR TI telemedical Expanders - Apply equivalent subjects
<i>S19</i>	AB telehome OR TI telehome Expanders - Apply equivalent subjects
<i>S18</i>	AB telecare OR TI telecare Expanders - Apply equivalent subjects
<i>S17</i>	AB ehealth OR TI ehealth Expanders - Apply equivalent subjects
<i>S16</i>	AB e-health OR TI e-health Expanders - Apply equivalent subjects
S15	(MH "Telepsychiatry") OR (MH "Telerehabilitation") Expanders - Apply equivalent subjects
<u>S14</u>	(MH "Telemedicine+") OR (MH "Telenursing") Expanders - Apply equivalent subjects
<i>S13</i>	(MH "Remote Consultation") Expanders - Apply equivalent subjects
<i>S12</i>	(MH "Teleconferencing") OR (MH "Telepsychiatry") OR (MH "Telenursing") OR (MH "Videoconferencing+") O
a - 1	(MH "Telehealth") Expanders - Apply equivalent subjects
<u>S11</u>	AB psychiatric day treatment OR TI psychiatric day treatment Expanders
<i>S10</i>	AB mental health consultation OR TI mental health consultation Expanders - Apply equivalent subjects
<u>S9</u>	AB psychiatric consultation OR TI psychiatric consultation Expanders - Apply equivalent subjects
<u>S8</u>	AB counseling psychology OR TI counseling psychology Expanders - Apply equivalent subjects
<i>S</i> 7	AB mental health counseling OR TI mental health counseling Expanders - Apply equivalent subjects
<i>S6</i>	(MH "Psychiatric Home Care") Expanders - Apply equivalent subjects
<i>S5</i>	(MH "Community Mental Health Services+") Expanders - Apply equivalent subjects
<i>S4</i>	(MH "Psychiatric Patients+") OR (MH "Psychiatric Units") OR (MH "Hospitals, Psychiatric") Expanders - App
	equivalent subjects
<i>S3</i>	(MH "Mental Disorders+") Expanders - Apply equivalent subjects
<i>S2</i>	(MH "Mental Health Services") Expanders - Apply equivalent subjects
<i>S1</i>	(MH "Psychiatry+") Expanders - Apply equivalent subjects

References for RCT filters applied in the search strategies:

Pupmed, Embase and Cinahl[1]

Web of science[2]

PsycInfo [3]

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- [2] "Searching for studies | Cochrane Ear, Nose and Throat." https://ent.cochrane.org/resources/searching-studies (accessed Aug. 29, 2021).
- [3] E. Mccaughan, K. Parahoo, I. Hueter, and L. Northouse, "Online support groups for women with breast cancer," *Cochrane Database Syst. Rev.*, vol. 2015, no. 4, Apr. 2015, doi: 10.1002/14651858.CD011652/EPDF/FULL.

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

			-
		Reporting Item	Page Number
Title		2	
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	"n/a"
Registration			
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	1,2,4
Authors			
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
	For peer	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3	Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	8
4 5 6	Amendments			
7 8 9 10 11 12		<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	1
13 14 15	Support			
16 17	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	8
18 19 20	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	8
20 21 22 23 24	Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	8
25 26	Introduction			
27 28 29 30	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	2,3,4
31 32 33 34 35	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	2,4
36 37	Methods			
38 39 40 41 42 43 44	Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4 , 5
45 46 47 48 49 50 51	Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
52 53 54 55 56 57 58	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	5
59 60		For peer	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3	Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	5,6
4 5 7 8 9 10	Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6
11 12 13 14 15 16 17	Study records - data collection process	<u>#11c</u>	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
18 19 20 21 22	Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
23 24 25 26 27	Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6
28 29 30 31 32 33 34	Risk of bias in individual studies	<u>#14</u>	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6
35 36 37 38	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	7
 39 40 41 42 43 44 45 	Data synthesis	<u>#15b</u>	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's T)	7, 8
46 47 48 49	Data synthesis	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	7, 8
50 51 52	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	7
53 54 55 56 57 58	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	8
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1 2 3 4 5	Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8
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Psychiatric treatment conducted via telemedicine versus inperson consultations in mood, anxiety and personality disorders: a protocol for a systematic review and metaanalysis

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ADMINISTRATIVE INFORMATION

Title Psychiatric treatment conducted via telemedicine versus in-person consultations in mood, anxiety and personality disorders: a protocol for a systematic review and meta-analysis

Registration This protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 2 July 2021 (Registration number CRD42021256357)

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Amendments Any deviation from the initial protocol during the review process will be documented in PROSPERO registry and reported in the final report.

Word Count 3087

ABSTRACT

Introduction Major advancements in technology has led to considerations how telemedicine (TM) and other technology platforms can be meaningfully integrated in treatment for psychiatric disorders. The COVID-19 pandemic has placed a further focus on use of TM in psychiatry. Despite the widespread use of TM, little is known about its effect compared to traditional in-person (IP) consultation. The objective of this systematic review is to examine if individual psychiatric outpatient interventions for adults using TM are comparable to IP in terms of (1) psychopathology outcomes, (2) levels of patient satisfaction, (3) working alliance, and (4) dropout from treatment.

Methods and analysis This review will only include randomized controlled trials for adult participants with mood disorders, anxiety, or personality disorders. The primary outcome is psychopathology, and secondary outcomes include patient satisfaction, treatment alliance, and dropout rate. Systematic searches were conducted in MEDLINE, APA PsycINFO, Embase, Web of Science, and CINAHL. The inverse-variance method will be used to conduct the meta-analysis. Effect sizes will be calculated as standardized mean difference (Hedges' g) for the primary outcome, mean difference (MD) for patient satisfaction and working alliance, and risk ratio (RR) for the dropout rate. Effect sizes will be supplemented with 95% CI. We will calculate the I² statistic to quantify heterogeneity and Chi2 statistic (χ^2) to test for heterogeneity for the primary outcome. Potential clinical and methodological heterogeneity moderators will be assessed in subgroup and sensitivity analysis. The risk of bias will be assessed by Cochrane Risk of Bias Tool 2, and confidence in cumulative evidence will be assessed by GRADE.

Ethics and dissemination No ethical approval is required for this systematic review protocol. Data sets will be deposited in the Zenodo repository. The findings of this study will be published in a peer-review scientific journal.

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Article summary

Strengths and limitations of this study

- This review will include randomized controlled trials to compare individual psychiatric treatment • using TM or IP for people with mood, anxiety, or personality disorders.
- Validated and standardized measures will be used to assess psychopathology, patient satisfaction • (CSQ-8) and working alliance (WAI) across all the studies.
- This systematic review will calculate and compare dropout rates between TM and IP treatment • formats. An outcome that has not previously been examined in a systematic review.
- The stringent eligibility criteria regarding study design, participants, interventions and outcome • measures will result in some studies being excluded.

INTRODUCTION

Telemedicine (TM) is, according to the world health organization (WHO), interpreted as "healing at a distance" that enables remotely-delivered treatment while the patient and clinician are in a different physical location. ¹ Various names have been suggested and used interchangeably in the scientific literature to describe TM. Telehealth, telepsychiatry, video consultation, video conference, telemental health, and teleconsultation, for example, are commonly used. Telemedicine is the broader term and covers synchronous (Video, Telephone) and asynchronous ("Store and forward," i.e., Emails, SMS) technologies. ²

Experimentation with TM in medical settings first began in the 1950s. These studies were based on a simple two-way closed-circuit television and TM was used for treatment and education purposes.³ Advances in technology and increasing access to the internet mean that TM can now be quickly accessed using a smartphone or other digital devices.^{4 5 6} Furthermore, the COVID-19 pandemic has led to the accelerated use of digital solutions in health care systems in many countries.^{7 8 9} Currently, there a number of large ongoing trials comparing TM to IP in populations of depression, anxiety, obsessive-compulsive disorder and perinatal women.^{10 11 12}

The use of TM in mental health services has several potential advantages such as making psychiatric services more accessible and flexible, reducing the cost of transport and time, reducing stigma, promoting patient autonomy, and providing an opportunity for people with mental health difficulties to engage with services if they find it challenging to attend in-person (IP) consultations.¹³ ¹⁴

There are also some potential disadvantages of TM, which include concerns about data security, technical obstacles, questions regarding the efficacy of interventions grounded in TM, which patient groups TM is most suitable for, concerns about establishing good working alliances, maintaining treatment engagement, and the allocation of resources of trained clinicians.¹⁵ ¹⁶ Different populations (eg: geriatric, suicidal or perinatal) can also experience a range of barriers and challenges using TM such as issues of privacy and safety, difficulty learning new technologies or the provision of care for acute mental health problems. ¹⁷ ¹⁸ ¹⁹

Over the last two decades, several systematic reviews have compared TM to IP within psychiatry.²⁰⁻²¹ These systematic reviews indicate that TM for psychiatric outpatients is equivalent to IP consultations regarding effectiveness (psychopathology, patient satisfaction, and working alliance). Unfortunately, the majority of these reviews have usually been descriptive in nature and included trials of varying quality. Furthermore many of the RCT's included in these reviews have been underpowered. Currently, there is a lack of quantitative analyses to determine the efficacy of psychiatric treatment provided by TM compared to IP formats.

Three meta-analyses conducted by Drago (2016), Batastini (2021), and Giovanetti (2022) have examined outcomes comparing TM to IP treatment.²² ²³ ²⁴ Drago et al. examined a wide range of interventions within psychiatry but excluded psychotherapeutic interventions. They found that TM was not inferior to IP across a range of mental health outcomes. Batastini et al. carried out a large review of TM and IP for a broad range of psychotherapeutic interventions within mental health and they found no significant differences in outcomes between the two treatment formats. Batastini et al. review included a range of study designs (randomized and non-randomized trials) and different treatment formats (individual and group) across a broad range of mental health related outcomes (symptoms, hospitalization, relapse, medication compliance). Giovanetti et al. conducted a systematic review and meta-analysis to examine the treatment effect for patients with depressive symptoms. Their meta-analysis included 11 RCT studies that directly compared individual psychotherapy through TM with IP and they found no significant differences in outcomes between the two treatment formats. Results from the three reviews conducted indicate that treatment using TM is comparable to IP treatment, although the three research groups also acknowledge a number of limitations with their respective

reviews. They recommend that further trials and reviews were necessary and highlight the need for more rigorous study designs, inclusion of a broader range of psychiatric disorders, clearly defined interventions and detailed diagnostic descriptions to develop the evidence base when comparing TM and IP interventions.

Satisfaction outcomes in studies comparing TM to IP in psychiatric outpatients have been assessed in a single meta-analysis by Hyler.²⁵ This review concluded that there were no differences in levels of patient satisfaction between TM and IP modalities although the authors noted that only a few studies used standardized satisfaction instruments. A number of studies applied ad hoc or untested satisfaction instruments, where the reliability or validity was not reported. It is essential to use standardized and empirically evaluated measures to allow meaningful comparisons between different studies.²⁶

Working alliance was assessed in meta-analysis conducted by Norwood (2018), that concluded that alliance in TM treatment was inferior to IP treatment.²⁷ This finding contrasts with other systematic reviews that suggest that alliance in individual treatment using TM was equal or better than IP treatment.²⁸ ²⁹ ²¹

Currently, there is no meta-analysis on dropout rates in treatment using TM compared and IP making it a research area that needs to be addressed.

Based on the current research examining interventions using TM compared to IP consultations, there is a need to conduct a meta-analysis covering a range of psychiatric disorders and focusing on multiple clinical outcomes. This meta-analysis will build upon previous research and address some of the current limitations in the literature by conducting a systematic review including studies with rigorous study design (only RCT's), defined clinical interventions (individual treatment), specific psychiatric populations (diagnoses of anxiety, depression or personality disorder) using standardized assessments for psychopathology, working alliance and treatment satisfaction. By pooling results from several studie

The specific objective of this systematic review is to examine if individual psychiatric outpatient interventions for adults conducted using TM are comparable to IP in terms of (1) psychopathology outcomes, (2) levels of patient satisfaction, (3) working alliance, and (4) dropout from treatment.

METHODS AND ANALYSIS This protocol will be conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P).³⁰ The PRISMA-P checklist can be found in the online supplemental file 1. The review has been registered in the PROSPERO International Prospective Register of Systematic Reviews (Registration number CRD42021256357). The anticipated start date is October 2022. The anticipated end date is April 2023.

Eligibility criteria will be based and restricted on the type of study, population, intervention, comparator, and outcomes of the studies.

Types of studies

Randomized controlled trials.

Types of Participants

Participants are (1) adults (>18 years), (2) receiving individual psychiatric ambulant treatment, and (3) diagnosed with mood disorders, anxiety, or personality disorders according to both the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) III, IV and 5 and the WHO's International Statistical Classification of Diseases (ICD) 9 or 10. Participants with comorbid diagnoses will also be included apart from those diagnoses covered in the exclusion criteria

Types of intervention

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Individual treatment through synchronous real-time video delivered sessions/consultations in outpatient settings. Treatment is defined as intervention involving psychotherapy, pharmacological treatment or psychoeducation.

Types of comparator/control

Individual treatment IP and same active treatment as the intervention group receives.

Types of Outcomes

Eligible studies have assessed psychopathology following a mental health service. The secondary outcome of interest includes (a) patient satisfaction, (b) working alliance, (c) and dropout rate.

Exclusion criteria

- Non-RCT studies
- Participant < 18 years
- Group therapy
- Different psychotherapy (treatments) approaches in intervention and control group.
- Trials involving populations that primarily treating psychotic disorders, mental retardation, bipolar disorders, alcohol abuse, and substance use disorders will be excluded.
- Trials using asynchronous communications systems as an intervention (E.g., mails and static website without video function) and telephone (only audio) as the intervention will not be included.

Information sources and search strategy

The first step in the systematic review has been a comprehensive search in electronic databases. The database search strings were created in January 2021 by AS with guidance from the information specialist Trine Kæstel, who has expertise in systematic review searching (Psychiatric Research Unit, Region Zealand). The database search strategy was developed with input from the project team. Search strategies are provided in the supplementary file 2.

The databases used for the searches are as follow; Medline (Pubmed interface, 1986 onwards), APA PsycINFO (OVID interface, 1967 onwards), Embase (OVID interface, 1974 onwards), Web of Science (Clarivate interface, 2001 onwards), and CINAHL (EBSCOhost interface, 1981 onwards).

Medical subject headings (MeSH) and text words related to the search terms "psychiatry" and "telemedicine" were used for developing the search string in MEDLINE. Both search terms- psychiatry and telemedicine-were then combined with [AND]. Specific syntax and subject headings were subsequently adapted individually to the different databases.

No language and date restriction was implemented in the search process. Due to the unmanageable results (>20.000 hits) in the preliminary search, Cochrane's highly sensitive search strategy filters identifying randomized trials has been applied in the final search string. Repeated search will be performed prior to the final analysis to identify further eligible studies. Unpublished studies will not be sought.

The second step in the search strategy will be a manual literature search to identify additional primary studies for the systematic review.

The third step will be scanning the reference lists of included studies or relevant reviews identified in the first and second steps.

Data management Records from the literature search will be exported to the reference manager Endnote X9.³¹ From Endnote records will be exported to Covidence. Covidence is a web-application tool that facilitates collaboration among the review team members during the study selection and data extraction process.³² Extracted data in Covidence will be exported to RevMan 5.4 for data analysis.³³

Selection process AS and SA will be responsible for the selection process. In the first step, the two authors will independently screen the title and abstracts of the records in Covidence to identify potentially eligible records. The Second step will be obtaining and screening full-text reports to decide if reports meet eligible criteria. Disagreement through the selection process will be resolved by discussion between the two authors. In case of continued disagreement despite discussion, a third reviewer, OJS will be consulted. The selection process- including exclusion reasons- will be documented in the PRISMA-P flow diagram. Inter-rater reliability will be measured by Cohen's kappa coefficient (κ) for the (1) title and abstract screening process and (2) full-text review process.

Data collection process AS and SFA will be responsible for the data collection process. Data extraction will be carried out through a standardized electronic data extraction form in Covidence. The data extraction form will initially be piloted on some reports, and the reviewers will meet and discuss the form before starting the review. Disagreement through the data collection process will be resolved by discussion between the two authors. In case of continued disagreement despite discussion, a third reviewer (OJS) will be consulted. If we encounter multiple reports of the same study, we will extract data from all reports into a single data collection form in Covidence.³⁴ Missing data will be obtained by contacting and requesting these data from the study authors.

Data items We will extract the following data items for each study: (a) study characteristics (authors, author contact details, aim of the study, trial design, location, trial size, sample size calculation, year of publication and country), (b) population characteristics (remote /rural area or urban, country, diagnosis/condition, comorbidity, mean age and gender) (c) intervention/control (internet connection speed, bandwidth, therapy type, number of consultation sessions and duration of consultation), (d) clinical outcome (assessments tool, psychopathology, satisfaction, alliance, and dropout rate). When reported in the studies, we will collect data from the "intention to treat" analysis; otherwise, per-protocol data will be collected. For crossover RCTs, only data before crossover will be used to prevent carryover effects and units of analysis errors.

Outcomes and prioritization The primary outcome in this review is psychopathology assessed by clinician or patient-rated scales. As we expect that different assessments tools have been used for measuring the primary outcome, we will priorities clinician rated scales and secondary patient-rated scales.

The secondary outcomes in the review will be (a) patient satisfaction, (b) working alliance, and (c) dropout rate. Satisfaction must be assessed by client satisfaction questionnaire-8 (CSQ-8)²⁶, and the working alliance must be assessed by the client working alliance inventory (WAI)³⁵ in the included studies. The dropout rate is defined as the number of participants not completing scheduled treatment course.

Risk of bias in individual studies AS and SFA will perform the risk of bias (quality) assessment in the individual studies. The revised Cochrane risk-of-bias tool for randomized trials (RoB 2)³⁴ will be applied. Our primary outcome –psychopathology- will be assessed for risk of bias in each study. The bias domain that will be assessed include (a) bias arising from the randomization process, (b) bias due to deviations from intended interventions, (c) bias due to missing outcome data, (d) bias in the measurement of the outcome, and (e) bias in the selection of the reported result. Overall risks of bias for each study outcome will be marked as: (1) "low risk of bias" if all domains are judged to be low, (2) "some concerns" if at least one domain are judged to raise some concerns but not to be at high risk of bias for any domain and (3) "high risk

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of bias" if any domain is judged to be at high risk of bias. Disagreement between the mentioned researchers regarding the risk of bias will be resolved through consensus or a third researcher (OJS). Covidence tool will be used to assess the risk of bias.

Data synthesis The general strategy for our data synthesis is to perform a quantitative synthesis (metaanalysis). A narrative synthesis will be performed if heterogeneity (I²) is substantially high and will include summary tables and descriptions of the findings. I² values will be judged as follows: 0% to 40% may represent little heterogeneity, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, and 75% to 100% represent considerable heterogeneity. Heterogeneity which is the percentage of variation across studies that is due to heterogeneity rather than chance will be grouped in (1) clinical, (2) methodological, and (3) statistical heterogeneity.³⁴ Clinical heterogeneity refers to the variation across studies regarding age, sex, diagnosis, treatment-site, and intervention characteristics (duration of intervention, number of interventions, and time interval between interventions). Methodological heterogeneity refers to the variability in the risk of bias and outcome measurement tools. Statistical heterogeneity refers to the differences in the intervention effects of each trial being evaluated.

Quantitative synthesis

We will use the inverse-variance method for carrying out the meta-analysis. Larger studies with less variance will be given more weight in the meta-analysis due to more precise effect size estimates than smaller studies. As we expect clinical and methodological heterogeneity in the pooled studies, we will use the random-effects model to obtain the overall effect size estimate. When heterogeneity is low a fixed-effect model will be chosen.

Continuous outcome measures

We will calculate the standardized mean difference (SMD) effect size for the primary outcome using Hedges' g formula. Because we intend to use different assessments tools to calculate the effect size for the primary outcome in each study, SMD will be statistically suitable for this. Forest plot will be used for presenting effect sizes and overall effect size. A 95% confidence interval will supplement the calculated effect sizes. Furthermore, we will calculate the I² statistic to quantify heterogeneity and Chi² statistic (χ^2) to test for heterogeneity (p \leq 0.1 significance level).

For the secondary outcomes- satisfaction and working alliance- we will calculate mean difference effect size (MD) as we have restricted these secondary outcomes to be assessed by a standardized tool (CSQ-8 and WAI). Therefore, standardizing is not needed to calculate the effect size across the studies. Beyond this, the same statistical approach for the primary outcome already described will be applied to the secondary outcomes satisfaction and working alliance.

We intend to combine"end of treatment" scores (post-intervention) and "change score" data (changes from baseline) to calculate the estimated overall effect size for both primary and secondary outcomes. This is a valid approach.³⁶ If the change score is not reported or cannot be calculated, post-intervention data will be used as the second choice.

Dichotomous outcome measures

We will calculate the risk ratio (RR) effect size and its 95% confidence interval for the secondary outcome dropout rate. Forest plot will be used to present effect sizes and overall effect size and supplemented with I^2 and χ^2 statistics. We define dropout as the number of participants not completing scheduled treatment courses, i.e., the difference in the number of participants who started the first treatment session (baseline) and completed the treatment course (posttreatment).

Additional primary outcome analyses (investigating heterogeneity)

For the primary outcome, a subgroup analysis (a) for different patient groups will be performed based on participant diagnosis as specified in the eligibility criteria, (b) sex, (c) ages, (d) length of treatment course/program, (e) therapy type, (f) settings (remote /rural area or urban) and (g) vulnerable populations (e.g., perinatal, ethnically/racially diverse and geriatric populations).

A sensitivity analysis will be performed to determine the robustness of the meta-analysis and will include:

1) removing low-quality studies and repeating the meta-analysis

2) testing for any possible difference between "end-of-treatment" scores and "change scores."

3) testing for whether the findings are sensitive to random-effects or fixed-effects models.

4) assessing the effect of the year of publication; a meta-regression will be performed, and a p-value for the regression will be calculated ($p \le 0.05$ significance level). The rationality for this meta-regression is to analyze if the technological or therapeutic evolution affects the primary outcome.

Meta-bias Publication bias will be assessed and will be done by visually assessing a funnel plot supplied by Egger's test.^{37 34}

Confidence in cumulative evidence We will use the GRADE approach (Grading of Recommendations Assessment, Development, and Evaluation) as recommended by Cochrane Collaboration to assess the confidence of the body of evidence.³⁴

Patient and Public Involvement No patients are involved.

Ethics and dissemination No ethical approval is required for this systematic review protocol. Data sets will be deposited in the Zenodo repository. The findings of this study will be published in a peer-review scientific journal. TR

STATEMENTS

Contributors AS is the guarantor of the protocol and wrote the first draft protocol.

ES, SFA, AS: developed the idea and rationale for the systematic review

OJS: Developed the idea for the protocol and provided statistical inputs

JAAS: Provided technological perspective and insight.

All authors revised and approved the final manuscript.

Competing interests None declared

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1 2		
3 4 5		Publisher – Clarivate Version: EndNote X9 Type: 64 bit.
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17 18 19	36.	Da Costa BR, Nüesch E, Rutjes AW, et al. Combining follow-up and change data is valid in meta- analyses of continuous outcomes: A meta-epidemiological study. <i>J Clin Epidemiol</i> . 2013;66(8):847- 855. doi:10.1016/j.jclinepi.2013.03.009
20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 .	37.	Egger M, Smith GD, Schneider M, Minder C. Papers Bias in Meta-Analysis Detected by a Simple, Graphical Test.

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		-
	Reporting Item	Page Number
Title	2	
Identification #1	a Identify the report as a protocol of a systematic review	1
Update <u>#1</u>	If the protocol is for an update of a previous systematic review, identify as such	"n/a"
Registration		
<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	1 , 2 , 4
Authors		
Contact <u>#3</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
For	eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3	Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	8
4 5 7 8 9 10 11 12 13	Amendments			
		<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	1
14 15	Support			
16 17	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	8
18 19	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	8
20 21 22 23 24	Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	8
24 25 26	Introduction			
27 28 29	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	2,3,4
30 31 32 33 34 35	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	2,4
36	Methods			
37 38 39 40 41 42 43 44 45 46 47 48 49 50 51	Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4 , 5
	Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
52 53 54 55 56 57	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	5
58 59 60		For peer	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3	Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	5,6
4 5 7 8 9 10	Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6
11 12 13 14 15 16 17	Study records - data collection process	<u>#11c</u>	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
18 19 20 21 22	Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
23 24 25 26 27 28	Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6
28 29 30 31 32 33 34	Risk of bias in individual studies	<u>#14</u>	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6
35 36 37 38	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	7
39 40 41 42 43 44 45	Data synthesis	<u>#15b</u>	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's T)	7, 8
46 47 48 49	Data synthesis	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	7, 8
50 51 52 53	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	7
53 54 55 56 57 58	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	8
59 60		For peer i	review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3 4 5	Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8
	evidence None The PRISMA- Commons Attributio https://www.goodrey Penelope.ai	on Licens ports.org	ration and explanation paper is distributed under the terms of the CC-BY. This checklist can be completed online using (, a tool made by the EQUATOR Network in collaboration with	e Creative
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	nterface
#	Searches
1	exp Treatment Effectiveness Evaluation/
2	exp Treatment Outcomes/
3	exp Placebo/
4	exp Followup Studies/
5	placebo*.mp.
6	random*.mp.
7	comparative stud*.mp.
8	(clinical adj3 trial*).mp.
9	(research adj3 design).mp.
10	(evaluat* adj3 stud*).mp.
11	(clinical adj3 trial*).mp.
12	(research adj3 design).mp.
13	(evaluat* adj3 stud*).mp.
14	(prospectiv* adj3 stud*).mp.
15	((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*)).mp.
16	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17	exp Psychiatry/
18	exp Mental Health/
19	exp Mental Disorders/
20	exp Mental Health Services/
21	mental health counseling.ab,sh,ti,tw.
22	mental health consultation.ab,sh,ti,tw.
23	psychiatric consultation.ab,sh,ti,tw.
24	psychiatric day treatment.ab,sh,ti,tw.
25	mental health care.ab,sh,ti,tw.
26	psychiatric home care.ab,sh,ti,tw.
27	"psychiatric outpatien*".ab,sh,ti,tw.
28	17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
29	exp Telemedicine/
30	exp Telepsychiatry/
31	exp Videoconferencing/
32	ehealth.ab,sh,ti,tw.
33	telecommunication.ab,sh,ti,tw.
34	telehealth.ab,sh,ti,tw.
35	telemental.ab,sh,ti,tw.
36	"telepsychiatr*".ab,sh,ti,tw.
37	"teletherap*".ab,sh,ti,tw.
38	"videoconferenc*".ab,sh,ti,tw.
39	videophone.ab,sh,ti,tw.
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•	liaison psychiatry/ or neuropsychiatry/ or psychosomatics/ or social psychiatry/ or telepsychiatry/
2	exp mental health/
3	mental disease/ or addiction/ or adjustment disorder/ or anxiety disorder/ or autism/ or behavior disorder/ or dissociative disorder/ or emotional disorder/ or mood disorder/ or neurosis/ or personality disorder/ or psychosis/ or schizophrenia spectrum disorder/
4	exp mental health service/
5	home mental health care/
6	"psychiatric consultation*".ab,kw,ti,tw.
7	mental health counseling.ab,kw,ti,tw.
8	psychiatric day treatment.ab,kw,ti,tw.
9	mental health care.ab,kw,ti,tw.
10	psychiatric home care.ab,kw,ti,tw.
11	psychiatric outpatient.ab,kw,ti,tw.
12	"psychiatric outpatient*".ab,kw,ti,tw.
13	mental health home care.ab,ao,kw,ti,tw.
14	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	telepsychiatry/
16	teleconsultation/ or telediagnosis/ or telemonitoring/ or telepathology/ or telepsychiatry/ or teleradiotherapy/ or telerehabilitation/ or teletherapy/
17	telehealth/
18	telecommunication/ or telemedicine/ or teleconsultation/ or telediagnosis/ or telepsychiatry/ or telerehabilitation/ or teletherapy/
19	videoconferencing/
20	"videoconferenc*".ab,ao,kw,ti,tw.
21	videophone.ab,ao,kw,ti,tw.
22	telehealth.ab,ao,kw,ti,tw.
23	telemental.ab,ao,kw,ti,tw.
24	ehealth.ab,ao,kw,ti,tw.
25	"teletherap*".ab,ao,kw,ti,tw.
26	telecommunication.ab,ao,kw,ti,tw.
27	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28	14 and 27
29	(Randomized controlled trial/ or Controlled clinical study/ or random\$.ti,ab. or randomization/ or intermethod comparison/ or placebo.ti,ab. or (compare or compared or comparison).ti. or ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. or (open adj label).ti,ab. or ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. or double blind procedure/ or parallel group\$1.ti,ab. or (crossover or cross over).ti,ab. or ((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant\$1)).ti,ab. or (assigned or allocated).ti,ab. or (controlled adj7 (study or design or trial)).ti,ab. or (volunteer or volunteers).ti,ab. or human experiment/ or trial.ti.) not (((random\$ adj sampl\$ adj7 ("cross section\$" or questionnaire\$1 or survey\$ or database\$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)) or (Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or (systematic review not (trial or study)).ti. or (nonrandom\$ not random\$) not randomi?ed controlled.ti,ab. or (random cluster adj3 sampl\$).ti,ab. or ((review.ab. and review.pt.) not trial.ti.) or ("we searched".ab. and (review.ti. or review.pt.)) or "update review".ab. or (databases adj4 searched).ab. or ((rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset\$1).ti. and animal experiment/) or (Anima
30	experiment/ not (human experiment/ or human/))) 28 and 29

Search Strategy for:	Medline
Pubmed Interface	

Query

((((((((trial [ti]) OR (randomly [tiab])) OR (clinical trials as topic [mesh: noexp])) OR (placebo [tiab])) OR (randomized [tiab])) OR (controlled clinical trial [pt])) OR (randomized controlled trial [pt])) NOT (animals [mh] NOT humans [mh]))

AND (("Psychiatry"[MeSH Terms] OR "Mental Disorders"[MeSH Terms] OR "Mental Health Services"[MeSH Terms] OR "Mental Health"[MeSH Terms] OR ("mental health counseling"[Title/Abstract] OR "mental health consultation"[Title/Abstract] OR "psychiatric consultation*"[Title/Abstract] OR "psychiatric day treatment"[Title/Abstract] OR "mental health care"[Title/Abstract] OR "psychiatric outpatient*"[Title/Abstract] OR "community mental health"[Title/Abstract]))

AND ("Telemedicine"[MeSH Terms] OR "Videoconferencing"[MeSH Terms] OR "Remote Consultation"[MeSH Terms] OR ("ehealth"[Title/Abstract] OR "telecare"[Title/Abstract] OR "teleconsultation*"[Title/Abstract] OR "telehome"[Title/Abstract] OR "telemedic*"[Title/Abstract] OR "telepsychiatr*"[Title/Abstract] OR "telemental"[Title/Abstract] OR "televideo"[Title/Abstract] OR "videoconferenc*"[Title/Abstract] OR "videophone"[Title/Abstract] OR "telehealth"[Title/Abstract] OR "telemental"[Title/Abstract] OR "ehealth"[Title/Abstract] OR "telehealth"[Title/Abstract] OR "telemental"[Title/Abstract] OR "ehealth"[Title/Abstract] OR "video conferencing"[Title/Abstract] OR "telecommunication*"[Title/Abstract] OR "teletherapy"[Title/Abstract]))))

Sea	arch Strategy for: Web Of Science
	urivate interface
#	Searches
1	(Psychiatr* OR (mental NEAR (health OR disorder* OR ill*)) OR (counseling NEAR psychology) OR (mental NEAR (counseling OR
	consultation*)) OR "psychiatric consultation*" OR "psychiatric day treatment" OR "psychiatric home care" OR "me
	ntal health service*")
2	(e-health OR telecare OR teleconsultation* OR telehome OR telemedic* OR telepsych* OR telemental* OR televideo* OR videoconference* OR videophone OR telehealth OR ehealth OR "video conferencing" OR Telecommunication* OR teletherap* OR teleconference*)
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	h Strategy for: Cinahl
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S55 S54	S31 AND S54 Expanders - Apply equivalent subjects
<u>S54</u>	S53 NOT S52 Expanders - Apply equivalent subjects S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 O
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S52	MH (human) Expanders - Apply equivalent subjects
S50	S47 OR S48 OR S49 Expanders - Apply equivalent subjects
S49	<i>TI (animal model*) Expanders - Apply equivalent subjects</i>
S49	MH (animal studies) Expanders - Apply equivalent subjects MH (animal studies) Expanders - Apply equivalent subjects
S47	MH animals+ Expanders - Apply equivalent subjects MH animals+ Expanders - Apply equivalent subjects
S46	AB (cluster W3 RCT) Expanders - Apply equivalent subjects
S45	<i>MH</i> (crossover design) <i>OR MH</i> (comparative studies) <i>Expanders</i> - Apply equivalent subjects
S44	AB (control W5 group) Expanders - Apply equivalent subjects
S44 S43	PT (randomized controlled trial) Expanders - Apply equivalent subjects
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S41	MH (sample size) AND AB (assigned OR allocated OR control) Expanders -Apply equivalent subjects
S40	TI (trial) Expanders - Apply equivalent subjects
S39	AB (random*) Expanders - Apply equivalent subjects
S38	TI (randomised OR randomized) Expanders - Apply equivalent subjects
S37	MH cluster sample Expanders - Apply equivalent subjects
S36	MH pretest-posttest design Expanders - Apply equivalent subjects
S35	MH random assignment Expanders - Apply equivalent subjects
<u>S34</u>	MH single-blind studies Expanders - Apply equivalent subjects
<i>S33</i>	MH double-blind studies Expanders - Apply equivalent subjects
<i>S32</i>	MH randomized controlled trials Expanders - Apply equivalent subjects
S31	S29 AND S30 Expanders - Apply equivalent subjects
<i>S30</i>	S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 O
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S29	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 Expanders - Apply equivalent subject
S28	AB teleconference OR TI teleconference Expanders - Apply equivalent subjects
S27	AB teletherapy OR TI teletherapy Expanders - Apply equivalent subjects
S26	AB telemental health OR TI telemental health Expanders - Apply equivalent subjects
S25	AB videophone OR TI videophone Expanders - Apply equivalent subjects
S24	AB videoconference OR TI videoconference Expanders - Apply equivalent subjects
S23	AB televideo OR TI televideo Expanders - Apply equivalent subjects
S22	AB telemental OR TI telemental Expanders - Apply equivalent subjects
S21	AB telepsychiatric OR TI telepsychiatric Expanders - Apply equivalent subjects
S20	AB telemedical OR TI telemedical Expanders - Apply equivalent subjects
S19	AB telehome OR TI telehome Expanders - Apply equivalent subjects
S18	AB telecare OR TI telecare Expanders - Apply equivalent subjects
<i>S17</i>	AB ehealth OR TI ehealth Expanders - Apply equivalent subjects
S16	AB e-health OR TI e-health Expanders - Apply equivalent subjects
S15	(MH "Telepsychiatry") OR (MH "Telerehabilitation") Expanders - Apply equivalent subjects
S14	(MH "Telemedicine+") OR (MH "Telenursing") Expanders - Apply equivalent subjects
<i>S13</i>	(MH "Remote Consultation") Expanders - Apply equivalent subjects
<i>S12</i>	(MH "Teleconferencing") OR (MH "Telepsychiatry") OR (MH "Telenursing") OR (MH "Videoconferencing+") O
	(MH "Telehealth") Expanders - Apply equivalent subjects
<i>S11</i>	AB psychiatric day treatment OR TI psychiatric day treatment Expanders
S10	AB mental health consultation OR TI mental health consultation Expanders - Apply equivalent subjects
S9	AB psychiatric consultation OR TI psychiatric consultation Expanders - Apply equivalent subjects
<i>S</i> 8	AB counseling psychology OR TI counseling psychology Expanders - Apply equivalent subjects
<i>S</i> 7	AB mental health counseling OR TI mental health counseling Expanders - Apply equivalent subjects
S6	(MH "Psychiatric Home Care") Expanders - Apply equivalent subjects
<i>S5</i>	(MH "Community Mental Health Services+") Expanders - Apply equivalent subjects
<i>S4</i>	(MH "Psychiatric Patients+") OR (MH "Psychiatric Units") OR (MH "Hospitals, Psychiatric") Expanders - App
	equivalent subjects
<i>S3</i>	(MH "Mental Disorders+") Expanders - Apply equivalent subjects
S2	(MH "Mental Health Services") Expanders - Apply equivalent subjects
SI	(MH "Psychiatry+") Expanders - Apply equivalent subjects

References for RCT filters applied in the search strategies:

Pupmed, Embase and Cinahl[1]

Web of science[2]

PsycInfo [3]

- W. L. Lefebvre C, Glanville J, Briscoe S, Littlewood A, Marshall C, Metzendorf M-I, Noel-Storr A, Rader T, Shokraneh F, Thomas J, "4.S1 Technical Supplement to Chapter 4: Searching for and selecting studies | Cochrane Training," 2021. https://training.cochrane.org/handbook/current/chapter-04-technical-supplement-searching-and-selecting-studies (accessed Aug. 29, 2021).
- [2] "Searching for studies | Cochrane Ear, Nose and Throat." https://ent.cochrane.org/resources/searching-studies (accessed Aug. 29, 2021).
- [3] E. Mccaughan, K. Parahoo, I. Hueter, and L. Northouse, "Online support groups for women with breast cancer," *Cochrane Database Syst. Rev.*, vol. 2015, no. 4, Apr. 2015, doi: 10.1002/14651858.CD011652/EPDF/FULL.