## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Mental health specialist video consultations for patients with depression or anxiety disorders in primary care: Protocol for a randomised controlled feasibility trial |
| **AUTHORS** | Tönnies, Justus; Hartmann, Mechthild; Wensing, M; Szecsenyi, Joachim; Icks, Andrea; Friederich, Hans-Christoph; Haun, Markus |

## VERSION 1 – REVIEW

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| **REVIEWER** | Terri Fletcher<br>Michael E. DeBakey VA Medical Center, United States |
| **REVIEW RETURNED** | 15-Mar-2019 |

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| **GENERAL COMMENTS** | This manuscript on a study protocol for a randomized controlled feasibility trial of telemental health consultations is generally well-written and addresses the important topic of increasing access to specialty mental health services in a thoughtful manner. The manuscript would benefit from greater detail regarding several aspects of the study procedures.<br><br>• Telemedicine is a broad term which encompasses both clinic-to-clinic service delivery (patient receives telehealth services at a community clinic) as well as video telehealth to home service delivery (patient uses a personal device to receive telehealth services in their own personal space). It appears that this article is referring to clinic-to-clinic service delivery. This needs to be clarified.<br>• Will the mental health specialists be paid? What percent of their effort is dedicated to this project? Where will the MHS offices be located? How will they document their services in the patients' medical records and/or coordinate care with the GP?<br>• What guidance will GPs be given on how to talk to potential participants about the study? GPs with little telehealth knowledge/experience will need direction on how to present this treatment option to their patients. Will they have brochures to offer patients? The way the treatment is introduced will greatly impact patients' receptivity to receiving telehealth services. The more structure and guidance you can provide GPs the better.<br>• How will interested participants signed the informed consent document? Will it be sent by mail or will it be signed at an in-person appointment?<br>• Which staff member is expected to help the patients get set up with the telehealth consultation? How will they be trained? How does this task fit in with their current roles at the practice?<br>• Regarding inclusion criteria: do patients need to exceed cut-offs on both the PHQ-9 and the GAD-7, or just one of the two? How is "insufficient treatment" defined? Does this include both medication and therapy? |

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| | • Who is conducting the assessments? How are they administered? By mail or by phone?<br>• More information about the treatment is needed. Which manual will be used? Is it one that is publicly available or has been used in prior studies or one that was specifically created for this study? The intervention doesn't appear to directly target anxiety or depression, so it is unclear to me why this treatment approach was chosen.<br>• What is the rationale for only interviewing ten patients? Rather than random selection, I would suggest purposive sampling stratified by practice site.<br>• The section on patient and public involvement states that "focus groups significantly impacted tailoring the intervention and study procedures". How so?<br>• Ethics and dissemination section – it appears that MHS will receive supervision on the clinical intervention. Are the supervisors experienced in telemedicine? If not, will supervisors and MHS be trained in best practices for telemedicine? |

**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1
Reviewer Name: Terri Fletcher

Institution and Country: Michael E. DeBakey VA Medical Center, United States Please state any competing interests or state 'None declared': None declared

This manuscript on a study protocol for a randomized controlled feasibility trial of telemental health consultations is generally well-written and addresses the important topic of increasing access to specialty mental health services in a thoughtful manner. The manuscript would benefit from greater detail regarding several aspects of the study procedures.

• Telemedicine is a broad term which encompasses both clinic-to-clinic service delivery (patient receives telehealth services at a community clinic) as well as video telehealth to home service delivery (patient uses a personal device to receive telehealth services in their own personal space). It appears that this article is referring to clinic-to-clinic service delivery. This needs to be clarified.

Authors' reply: We clarified this aspect and mention the setting in a short sentence on page 5-6: "The junior research group PROVIDE (ImPROving cross-sectoral collaboration between primary and psychosocial care: An implementation study on VIDEo consultations) aims to define, tailor, and evaluate a PCBH model compatible with small and/or remote GP offices where the patient will receive the telemedical service. In contrast, the MHS will be located in her/his office/private practice or a suitable, designated room at home."

• Will the mental health specialists be paid? What percent of their effort is dedicated to this project?

Authors' reply: We added two sentences on page 7 to elaborate on these aspects: "The MHS will participate in the study as freelancers and will be paid per session according to the current fees for psychotherapy as reimbursed by the German statutory health insurance. For the therapists, expected time expenditure will be approximately six hours per week (four hours for consultations, 1.5 hours for supervision)."

• Where will the MHS offices be located?

Authors' reply: We have specified this on page 9 as follows: "The patient will be in the general practice and the psychotherapist either in her or his office private practice, in a suitable, designated room at home or in a therapy room at the HIP."

- How will they document their services in the patients' medical records and/or coordinate care with the GP?

Authors' reply: We have tried to clarify this aspect in the following sentence on page 11: "After the last consultation with the patient the MHS will send a written case summary to the general practitioner which will be attached to the medical record in the GP practice and on which, if needed, further clarifications on follow-up procedures between GPs and MHS can be based."

- What guidance will GPs be given on how to talk to potential participants about the study? GPs with little telehealth knowledge/experience will need direction on how to present this treatment option to their patients. Will they have brochures to offer patients? The way the treatment is introduced will greatly impact patients' receptivity to receiving telehealth services. The more structure and guidance you can provide GPs the better.

Authors' reply: As we now describe on page 9, we will conduct on-site training sessions with the GPs and provide each practice with jointly designed brochures and waiting room posters both tailored to the respective practice.

- How will interested participants signed the informed consent document? Will it be sent by mail or will it be signed at an in-person appointment?

Authors' reply: After we will have provided extensive information on the study and clarified any questions in a call, the patient will send back the signed document to the study team. We have added this aspect to the recruitment section (p. 7).

- Which staff member is expected to help the patients get set up with the telehealth consultation? How will they be trained? How does this task fit in with their current roles at the practice?

Authors' reply: On page 9, we provide a more detailed description on how the staff will be prepared to handle the video consultations, and we added two references explaining that there is no evidence supporting the necessity of a more comprehensive special training for telehealth interventions: "We will train the clinicians how to set-up the consultations technically. Although, is might be the first time for them to deal with video based telemedicine, "[…]there is no evidence to suggest prohibiting trainees or clinicians from engaging in telehealth if they are otherwise qualified [26]. We will ensure that every practice will nominate one team member who will be responsible for initiating video consultations and who will serve as contact person for MHS, patients, and the study team. Applying a training that primarily targets technical competency, we are confident that we will minimize potential difficulties with handling video consultations and consequently minimize task-related expenses. In fact, technical competency is regarded as crucial for successfully implementing telepsychiatry services[27]."

- Regarding inclusion criteria: do patients need to exceed cut-offs on both the PHQ-9 and the GAD-7, or just one of the two?

Authors' reply: To be eligible, patients will only need to exceed at least one of the two cut-offs. The inclusion and exclusion criteria section (page 8, first paragraph) now says "[…] exceed cut-offs of 9

points a) for the Patent Health Questionnaire (PHQ-9) and/or b) for the Generalized Anxiety Disorder 7 (GAD-7)[24], respectively […]"

- How is "insufficient treatment" defined? Does this include both medication and therapy?

Authors' reply: We are particularly thankful for this remark. In the inclusion and exclusion criteria section (page 8, first paragraph), we now state that "[…] 2) currently have no or as yet insufficient treatment (psychotherapy, psychopharmacotherapy, or both) or difficulty with adherence […]

- Who is conducting the assessments? How are they administered? By mail or by phone?

Authors' reply: We included a more detailed description of the assessments/measurements. With respect to the screening we added on page 10: "To screen patients using the PHQ-9 and GAD-7, the study team will conduct a standardised Computer Assisted Telephone Interviews." On page 12 we added the following: "As part of the blind outcome assessment, two research assistants, blinded to participant allocation, will conduct the post measurement in telephone interviews with the participants. In line with current recommendations, we specifically will make sure that the outcome assessors will not be present when discussing individual patients and avoid mentioning any names or assigned treatments[35]. In the case of unintentional unblinding during the assessment the assessors will document how and at which point the unblinding unfolded. Hence, we will be able to subsequently determine the extent to which the assessment was actually blind." On page 10, we have also clarified that the patients will mail the completed baseline questionnaires back to the study team.

- More information about the treatment is needed. Which manual will be used? Is it one that is publicly available or has been used in prior studies or one that was specifically created for this study? The intervention doesn't appear to directly target anxiety or depression, so it is unclear to me why this treatment approach was chosen.

Authors' reply: We now do provide more information about the treatment (page 10/11) und the translated stage I intervention manual (appendix 1) that will be used at this point of the study. Therein, we elaborate on how the intervention will target anxiety and/or depression in primary care. We compiled the manual specifically for this study.

- What is the rationale for only interviewing ten patients?

Authors' reply: We consider ten out of 25 possible patients (only intervention patients will be interviewed) just enough to get a broad overview of potential problems by conducting the intervention (we based our rationale on Hennink et al. 2017, DOI: 10.1177/1049732316665344). Given the resources available in this feasibility trial, we will refrain from interviewing significantly more patients.

- Rather than random selection, I would suggest purposive sampling stratified by practice site.

Authors' reply: Thank you very much for this helpful suggestion. It sparked a fruitful discussion in the study team, so that we have decided to conduct purposive sampling stratified by practice site, patient age, and patient technology commitment.

- The section on patient and public involvement states that "focus groups significantly impacted tailoring the intervention and study procedures". How so?

Authors' reply: We have added examples on how the focus groups' results contributed to the set-up of the feasibility trial on page 15: "We analysed and interpreted the results within two in-depth discussions within the study team. Main aspects and suggestions have been incorporated into the

handbook for GPs and the study manual for MHS that provide guidance regarding the study procedures and the intervention. Examples which have been transferred from focus groups' results are that 1) the appointment management were put into the hands of the MHS, 2) fixed time slots will be used, and 3) each patient will continuously consult with the identical MHS."

- Ethics and dissemination section – it appears that MHS will receive supervision on the clinical intervention. Are the supervisors experienced in telemedicine? If not, will supervisors and MHS be trained in best practices for telemedicine?

Authors' reply: On page 9, second paragraph, we now describe that we have conducted a 1-day training based on the existing recommendations which included 1) an introduction to the research project, 2) a detailed description of the study procedures, 3) a step-by-step instruction on the handling of video consultations (e.g., room setup and technical aspects), 4) an introduction to the intervention, and 5) a familiarization with the respective general practice. Additionally, all best practices will be laid out in the study manual for MHS and supervisors.