UKE Paper of the Month November 2024

Effect of the i2TransHealth e-health intervention on psychological distress among transgender and gender diverse adults from remote areas in Germany: a randomised controlled trial

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ABSTRACT:

Background: Transgender and gender diverse (TGD) people in remote areas face challenges accessing health-care services, including mental health care and gender-affirming medical treatment, which can be associated with psychological distress. In this study, we aimed to evaluate the effectiveness of a 4-month TGD-informed e-health intervention to improve psychological distress among TGD people from remote areas in northern Germany.

Methods: In a randomised controlled trial done at a single centre in Germany, adults (aged ≥18 years) who met criteria for gender incongruence or gender dysphoria and who lived at least 50 km outside of Hamburg in one of the northern German federal states were recruited and randomly assigned (1:1) to i²TransHealth intervention or a wait list control group. Randomisation was performed with the use of a computer-based code. Due to the nature of the intervention, study participants and clinical staff were aware of treatment allocation, but researchers responsible for data analysis were masked to allocation groups. Study participants in the intervention group (service users) started the i²TransHealth intervention immediately after completing the baseline survey after enrolment. Participants assigned to the control group waited 4 months before they were able to access i²TransHealth services or regular care. The primary outcome was difference in the Brief Symptom Inventory (BSI)-18 summary score between baseline and 4 months, assessed using a linear model analysis. The primary outcome was assessed in the intention-to-treat (ITT) population, which included all randomly assigned participants. The trial was registered with ClinicalTrials.gov, NCT04290286.

Findings: Between May 12, 2020, and May 2, 2022, 177 TGD people were assessed for eligibility, of whom 174 were included in the ITT population (n=90 in the intervention group, n=84 in the control group). Six participants did not provide data for the primary outcome at 4 months, and thus 168 people were included in the analysis population (88 participants in the intervention group and 80 participants in the control group). At 4 months, in the intervention group, the adjusted mean change in BSI-18 from baseline was –0·65 (95% CI –2·25 to 0·96; p=0·43) compared with 2·34 (0·65 to 4·02; p=0·0069) in the control group. Linear model analysis identified a significant difference at 4 months between the groups with regard to change in BSI-18 summary scores from baseline (between-group difference –2·98 [95% CI –5·31 to –0·65]; p=0·012). Adverse events were rare: there were two suicide attempts and one participant was admitted to hospital in the intervention group, and in the control group, there was one case of self-harm and one case of self-harm followed by hospital admission.

Interpretation: The intervention was clinically significant in averting worsening psychological distress in service users, outperforming the wait list control group. These findings support the effectiveness of e-health services in TGD health care, specifically for people from remote areas.

STATEMENT:

We believe our paper is the paper of the month as it is the first randomised controlled trial (RCT) exclusively focusing on transgender and gender diverse (TGD) people directly in a health-care setting. In doing so, we are addressing a critical gap in service provision, especially for TGD people from remote areas, and demonstrating how a university medical centre can effectively meet this need, including in overcoming barriers to e-health-care. The project also serves as an excellent example of the importance

of exceptional interdisciplinary and interprofessional collaboration across numerous clinical and scientific roles within the university setting. Overall, this study exemplifies high-quality, evidence-based research with great potential to drive meaningful improvements in care by providing specialised university medicine to remote areas.

BACKGROUND:

This work was performed at the Institute for Sex Research, Sexual Medicine, and Forensic Psychiatry in close collaboration with researchers from the Institute of Medical Biometry and Epidemiology and the Department of Psychiatry and Psychotherapy. The PI, PD Dr. Timo Nieder leads the research group Transgender and has a strong research output in the field of Transgender Care. Both Co-PIs, Prof. Dr. Peer Briken and Dr. Arne Dekker have EU-wide expertise in clinical trials in the field of Sex Research. The study was funded by the Innovation Committee at the Federal Joint Committee.