

focused on university students as they are particularly at risk for developing CMDs.

**Objectives:** The aim of this study was to evaluate experiences with the smartphone-based DTx *elona therapy* among university students with mild to moderate depression or anxiety symptoms for the use within bCBT.

**Methods:** Semi-structured interviews were conducted via video-conference between January and April 2022 with N = 102 students from universities in North Rhine-Westphalia, Germany, after they had received weekly individual CBT sessions (25 minutes each) via videoconference for six weeks and regularly used the depression (N = 67) or anxiety module (N = 35) of the DTx. Interviews were coded according to the approach of grounded theory.

**Results:** In general, most participants stated that they benefitted from the bCBT program. Many highlighted the intuitive handling of the DTx and indicated that they perceived it as useful for structuring their therapy progress. As other benefits, participants listed e.g., increased self-reflection and disorder-specific knowledge as well as the transfer of the content of therapy sessions into their daily life. Participants differed with respect to the preferred design of the DTx. While some liked the clean look, others would have favoured more colours. Participants mentioned time constraints, data security concerns or the feeling of being left alone with potentially arising emotions while working on tasks for the next therapy session as possible barriers to the usage of DTx.

**Conclusions:** Interviewed participants mostly had positive attitudes toward *elona therapy* as part of the bCBT program. Our study shows that DTx as part of bCBT can be perceived as helpful tools to accompany university students with mild to moderate anxiety or depression symptoms in their daily life.

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## EPP0690

### Reliability of electronic patient reported outcomes vs. clinical assessment

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**Introduction:** The importance of inter-scale and inter-rater reliability is a well-studied factor in maintenance of data consistency in clinical research. The use of patient reported outcomes poses another risk for compromising data integrity, as some studies show that patients tend to report their symptoms differently in direct clinician-lead interview and self-administered questionnaires. Additionally, as technology is advancing and digital endpoints in CNS clinical trials are becoming a reality, we need to further evaluate if the digital means of self-reporting (e.g., mobile app questionnaires) per se could potentially be a contributing factor in data inconsistency.

**Objectives:** To assess reliability between clinician-assisted evaluation and electronic patient reported outcomes of depressive and anxiety symptoms.

**Methods:** Patients not previously diagnosed with depression or anxiety disorders were asked to complete PHQ-9 and/or GAD-7,

both verbally administered by a physician. Within 24 hours they were asked to complete a digital form of the same questionnaires.

**Results:** The analysis of 40 completed double assessments showed no correlation for depressive symptoms presence and severity measured by clinician-lead evaluation and electronic patient reported outcomes (Spearman rho = + 0.191, p=0.686), and poor correlation for anxiety symptoms (Spearman rho = + 0.466, p=0.080).

**Conclusions:** Many factors interfere with data consistency in clinical research, thus the methods and means of evaluation need to be taken into consideration. The reliability of electronic patient reported outcomes needs to be further assessed and preferably cross-checked by using other validated methods of assessment.

**Disclosure of Interest:** None Declared

## EPP0691

### The EXPERIENCE system for the investigation of behavioral differences between depressed and healthy-control participants in Virtual Reality

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**Introduction:** The EXPERIENCE project aims to enable the creation and sharing of extended-personal realities in virtual reality (VR). Currently, software and hardware technology are under development, that will automatically generate VR environments based on neurophysiological, psychological, cognitive, and behavioral data to support not only the recording of personal experiences but the transmission as well to another user. Potential use cases include enhanced treatment and the assessment of symptom severity of affective disorders.

**Objectives:** The objective is to design and create a virtual reality environment that enables the identification of between-group differences in behavioral measures when comparing depressed and healthy-control participants.

**Methods:** We conducted a literature review to identify measures that can be implemented in VR and have the potential to show differences between depressed and healthy-control participants. PubMed and ResearchGate databases were screened to identify potential cognitive tasks. A selection protocol was developed considering effect size, homogeneity of results, risk for cybersickness, cognitive demand, domain heterogeneity, and VR compatibility to choose 4 out of the 47 initial tasks. In addition to the cognitive tasks, behavior measures were considered as well and a virtual environment has been equipped to assess (1) exploratory behavior; (2) engagement with emotionally valenced stimuli (via eye-tracking); (3) metacognitive sensitivity, (4) persistence/grit, and (5) possible effects of mood induction.

**Results:** Based on the above review, a virtual environment has been developed which is composed of four rooms and a hallway where the starting point is. After an initial tutorial on how the environment/controllers work participants are free to explore and instructions are only provided for the specific cognitive tasks which have to be solved to open the doors and move between rooms. The rooms are equipped with numerous interactive objects and images with

varying emotional valence. The engagement with the environment and general activity are continuously recorded and can be retrieved for analyses after participants exit the environment.

**Conclusions:** If the controlled VR environment will be proven effective for the assessment of depressive symptoms in future studies, the EXPERIENCE system could incorporate direct and objective behavioral measures into the assessment depressive symptoms. Consequently, the system has the potential to support the clinical diagnosis of affective disorders.

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## EPP0692

### iSupport for Dementia: an analysis of clinical trial records

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**Introduction:** Dementia has a significant psychological and emotional impact on families, especially for caregivers of people living with dementia. In this perspective, the World Health Organization has developed iSupport for Dementia, an online training and skills program to prevent and/or reduce mental health problems associated with the provision of care and improve the quality of life of caregivers. It is being translated and adapted in different countries and as of August 2022, 31 adaptations using 27 different languages were in progress. However, the availability of the program should only be carried out after evaluating its effects on caregivers' mental health outcomes (such as burden, depressive and anxious symptoms, quality of life, among others).

**Objectives:** To analyze randomized clinical trial protocols to assess the effects of the iSupport program in different countries.

**Methods:** This is a data survey carried out in October 2022 on clinical trial registry platforms Clinical Trials, The Brazilian Registry of Clinical Trials, Cochrane Central Register of Controlled Trials, Netherlands Trial Register and Australian New Zealand Clinical Trials Registry by two independent researchers. Descriptive analysis were performed for sample size, primary outcomes, secondary outcomes and intervention design.

**Results:** Seven clinical trial registries were identified, conducted in Australia/China, Brazil, Great Britain, the Netherlands, India, Japan and Portugal, published in English, from 2018 to 2022. The sample size ranged from 184 to 390 participants. Regarding the primary outcomes linked to the effect of using iSupport, five countries will analyze burden, anxiety and depression. Only in Australia/China and the Netherlands, the primary outcome will

be quality of life and stress, respectively. Secondary outcomes vary between studies, with measures of quality of life (n=6), self-efficacy (n=4), program usability (n=4), cognition and problematic behaviors (n=3), attitudes (n=3), quality of support (n=3), positive aspects of care (n=2), knowledge, competence, resilience and informal costs of care (n=1). Most studies will carry out assessments at baseline, 3 and 6 months after the intervention, with the exception of Japan that will perform at baseline and at 1 and 3 months after the intervention and 6 months.

**Conclusions:** Analysis of the effectiveness of iSupport is one of the World Health Organization guidelines for countries that are culturally adapting this program. Brazil is the only country in Latin America with a clinical trial registration so far. Burden, anxiety and depression are outcomes considered by most countries. The results could provide evidence to strengthen and expand the possibilities for collaboration between researchers, as internet-based interventions have shown promising results on the mental health and well-being.

**Disclosure of Interest:** None Declared

## EPP0693

### Effectiveness of an e-health system on depression among patients with somatic disorders

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**Introduction:** Patients with severe somatic conditions frequently develop depressive symptoms, with a reduction in quality of life, sleep disturbances and suicide as some of the most serious consequences. However, there is a lack of evidence-based interventions to reduce this comorbidity. The NEVERMIND system aims to address this issue by collecting biomedical and psychometric data through a smart shirt and questionnaires, which are used to predict patients' depressive symptoms. Based on the predictions, patients are offered personalised feedback to self-manage their mental health symptoms in the form of lifestyle behavioural advice, mindfulness-based therapy, and cognitive behavioural therapy.

**Objectives:** The primary objective was to assess the effectiveness of the NEVERMIND system in reducing depressive symptoms in patients with somatic conditions in comparison to treatment as usual. Some of the secondary objectives were to examine the NEVERMIND system's effectiveness in preventing new depressive symptoms, sustaining the effects of the intervention at 24 weeks post-baseline, and reducing suicide ideation.

**Methods:** For this pragmatic randomised controlled trial, 425 patients diagnosed with myocardial infarction, breast or prostate cancer, kidney failure, or lower limb amputation were recruited from hospitals in Turin, Pisa and Lisbon. Data from clinical interviews and structured questionnaires was collected at baseline, 12 weeks, and 24 weeks. The primary outcome was depressive symptoms at week 12 as measured by the Beck Depression Inventory II (BDI-II), while secondary outcomes included prevention of depressive symptoms, suicide ideation, self-reported general interest, satisfaction with daily life, illness perception, self-compassion, and the sustainability of the system's effect at 24 weeks post-baseline. The intention-to-treat analyses included all patients, while the per-protocol analyses included 333 patients.