SIMPAQ validation protocol

Aim: To determine the reliability and validity of the SIMPAQ among mental health service users against an objective measure of physical activity (accelerometer).

Hypothesis: We hypothesise that the SIMPAQ will demonstrate acceptable reliability and criterion validity (i.e. correlation > 0.3 or above for total physical activity) against the objective measure (accelerometer).

Eligibility criteria: Potential participants will be identified and referred to the researcher by treating clinicians at each site. The researcher at each site will subsequently provide details of the study methodology to potential participants and obtain written informed consent. Eligible participants will be a) aged 18-65 years, b) a current patient of one of the treatment facilities identified as being a research site c) meet Diagnostic and Statistical Manual of mental disorders criteria and/or ICD-10 criteria for a mental disorder. Potential participants will be excluded if there is evidence of significant cardiovascular, neuromuscular or endocrine disorders limiting regular ambulation (as per American College of Sports Medicine absolute contraindications to exercise); if they have a current diagnosis of anorexia nervosa or bulimia; have a current diagnosis of an organic brain disorder; estimated IQ < 70 or MoCA score <=26 (some people with Severe Mental Illness may score less than 26 on the MoCA as a consequence of the illness rather than indicating a separate neurocognitive disorder. When the score indicates a separate neurocognitive disorder this would lead to them being excluded).

Sample size: The expected total number of participants is n=1000, recruited from multiple sites. This target is based on previous validation studies of physical activity questionnaires (e.g. Craig et al 2003 Medicine & Science in Sports and Exercise Science) and allows for exploratory sub-group analysis to be conducted based on diagnostic groups, demographics and geographical location.

Methodology: Potential participants will be identified and referred to the research team by treating clinicians at each site. Patients will be approached by a researcher not involved in the direct care of the patient, and will be informed that the decision to participate will not have any impact on the treatment they receive. The research officer at each site will subsequently obtain written informed consent and details of the study methodology will be explained. The research officer will directly obtain demographic and diagnostic information as per the SIMPAQ Demographic & Diagnostic Data Sheet that includes sex, living situation, education, employment status, smoking status, psychiatric diagnoses, somatic co-morbidities and medication usage. The research officer will directly measure anthropometric outcomes (height and weight).

Additional cross-sectional assessments to be assessed at baseline include:

- DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure—Adult (23 items; 6 minutes)
- Montreal Cognitive Assessment (MoCA) (10 minutes)

Participants will also complete the SIMPAQ together with the research officer through a structured interview, as outlined in the SIMPAQ manual. The SIMPAQ is a 5 –item clinical tool designed to assess physical activity among populations at high risk of sedentary behaviour, such as those experiencing mental illness. Completion of the SIMPAQ takes between five and 10 minutes. Outcomes assessed include minutes of sedentary behaviour per day, minutes of exercise per day, minutes of walking per day and minutes of incidental physical activity per day.

Participants will then be given a tri-axial accelerometer (ActiGraph GT3X or GT3X+), which is a small device worn around the waist to provide an objective measure of physical activity. Participants will wear the monitor during waking hours for a total of seven days. After the seven-day period, participants will complete the SIMPAQ again with the research officer to

assess test-retest reliability. All participants will be engaged in treatment at the relevant sites at the time of recruitment into the study. As such all participants will be receiving usual care involving any combination of pharmacological, psychotherapeutic and group based treatments.

Data storage and analysis: De-identified data will be entered into an online portal called Centrepoint designed specifically by the accelerometer manufacturer (Actigraph), for the purpose of study coordination. Centrepoint provides a secure portal by which all data can be collated. Site coordinators will be provided with unique password protected access to the Centrepoint site. Patients will be assigned a unique project ID at entry into the study. This ID will be used to identify individual data at all stages of the project. Only the PI at each site will have access to the corresponding personal identification data linked to each project ID. All computer files will be password protected and all paper files will be stored in a locked filing cabinet. In order to determine the concurrent validity of the SIMPAQ questionnaire, correlation coefficients will be calculated between the SIMPAQ items for total physical activity and physical activity as recorded by the accelerometer. Correlation coefficients will also be calculated for the SIMPAQ walking time item and sedentary time item and compared to the accelerometer. Anthropometrical, diagnostic, cognitive capacity and symptom severity data will be analysed according to groups allowing for exploratory analysis of the SIMPAQ validity to be conducted. Data will be analysed using SPSS v22.