

**Targeting Physical Health in Schizophrenia:
Physical Activity Can Enhance life
(PACE-Life)**

Data Analytic Plan

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PACE-Life Open Trial CT.gov Submission

Primary Outcome Measures :

1. Mean difference in participant's total distance during 6-minute walk test [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
The 6-minute walk test (6MWT) will be used to measure cardiorespiratory fitness (CRF) during which individuals will be asked to walk continuously for six minutes on a flat, indoor surface around cones (separated by 100ft). The possible distance range is 400 meters to 650 meters. Higher scores reflect better outcomes (greater physical fitness).

Secondary Outcome Measures :

1. Mean difference Overall UCLA Loneliness Scale Score [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in overall score from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). The UCLA Loneliness scale is a 20 item scale. Answers are on a 4 point scale with options "I often feel this way," "I sometimes feel this way," "I rarely feel this way," and "I never feel this way." Possible scores range from 20 to 80. Higher scores reflect worse outcomes (greater feelings of loneliness).
2. Mean difference Overall PANSS score [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in the overall score from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). The PANSS is a semi-structured interview using a 30-item scale to evaluate the presence, absence and severity of Positive, Negative and General Psychopathology symptoms of schizophrenia. All 30 items are rated on a 7-point scale (1 = absent; 7 = extreme). Possible scores range from 30 to 210. Higher scores reflect worse outcomes (i.e. greater symptoms of psychosis).
3. Mean difference in body mass index (BMI) [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in body mass index (BMI) from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). BMI ranges from 14 to 54. Higher scores reflect worse outcomes (i.e. greater body mass).
4. Mean difference in diastolic blood pressure change [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)] Mean difference in diastolic blood pressure change from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). Diastolic blood pressure ranges from ≤ 70 to higher than 120mmHg. Higher scores reflect worse outcomes (i.e. higher diastolic blood pressure)
5. Mean difference in systolic blood pressure change [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in systolic blood pressure change from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). Systolic blood pressure ranges from ≤ 120 to higher than 140mmHg. Higher scores reflect worse outcomes (i.e. higher systolic blood pressure)

5. Mean difference in resting heart rate change [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in resting heart rate change from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). Heart rate ranges from ≤ 60 to higher than 100. Higher scores reflect worse outcomes (poorer heart condition)
6. Mean difference in waist circumference [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in waist circumference from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). Waist circumference ranges \leq than 94cm for males and $<$ than 80 for females to higher than 102cm for males and 88cm for females . Higher scores reflect worse outcomes (i.e. greater waist circumference = disease development risk).
7. Mean difference in weight [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in weight from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). Weight ranges from 45 to 130 kilograms . Higher scores reflect worse outcomes (i.e. greater weight).

Intermediate Target Measures:

1. Mean difference in weighted average motivation score (relative autonomy index) on the Behavioral Regulation Exercise Questionnaire (BREQ-2) [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in weighted average motivation score (relative autonomy index) from baseline to end of intervention (24 weeks) and to last study visit (up to 28 weeks). The BREQ-2 is a 19 item self-report scale. Answers are on a 5 point Likert scale ranging from 0 to 4. 0 corresponds to "not true for me" and 4 corresponds to "very true for me." Possible scores range from -24 to +20. Higher scores reflect better outcomes (higher autonomous motivation to exercise).
2. Mean difference in subscale scores on the Basic Psychological Needs in Exercise Scale [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in subscale scores of autonomy, relatedness, and competence from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). 2. The BPNE is an 11 item self-report scale. Answers are on a 5 point Likert scale ranging from "I don't agree at all" to "I completely agree." Possible scores for each subscale range from 1 to 5. Higher scores reflect better outcomes (i.e more psychological needs being met through exercise)
3. Mean difference in subscale scores on the Basic Psychological Need Scale – in General (BPNS) [Time Frame: Baseline, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in subscale scores of autonomy, relatedness, and competence from baseline to end of intervention (24 weeks) and last study visit (up to 28 weeks). 2. The BPNS is a 21-item self-report scale. Answers are on a 7 point Likert scale ranging from "Not at all true" to "Very true." Possible scores for each subscale range from 1 to 7. Higher scores reflect better outcomes (i.e more psychological needs being met)

Proximal Outcome Measures:

1. Mean difference in daily steps from Fitbit Devices [Time Frame: Week 1, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in steps/day from week 1 to end of intervention (24 weeks) and to last study visit (up to 28 weeks). Fitbit devices record steps taken. Possible scores range from 300 to 50,000. Higher scores reflect better outcomes (higher steps/day).
2. Mean difference in minutes spent walking from Fitbit Devices [Time Frame: Week 1, end of intervention (24 weeks), and the last study visit (Up to 28 weeks)]
Mean difference in weekly minutes spent walking from week 1 to end of intervention (24 weeks) and to last study visit (up to 28 weeks). Fitbit devices record minutes spent walking in bouts of 15 minutes. Possible scores range from 0 to 5,000. Higher scores reflect better outcomes (higher weekly minutes spent walking).