

SKIP (Supporting Kids with diabetes In Physical activity): Feasibility of a randomised controlled trial of a digital intervention for 9-12 year olds with type 1 diabetes mellitus.

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Introduction: Physical activity is important for children with type 1 diabetes mellitus (T1DM) but it is unclear whether interventions delivered online are feasible, acceptable to patients and efficacious. The aim was to assess the feasibility and acceptability of an internet-based physical activity and self-monitoring programme for children with T1DM recruited through hospital paediatric diabetes clinics, and of a randomised controlled trial (RCT) to evaluate efficacy.

Methods: Forty-nine children aged 9-12 with T1DM were randomly assigned to usual care only or to an interactive intervention group combining a website (STAK-D) and a PolarActive activity watch (PAW; Polar Electro (UK) Ltd.) alongside usual care. Participants completed self-report measures on their health, self-efficacy and physical activity at baseline (T0), eight weeks (T1) and six months (T2). They also wore a PAW to measure physical activity for one week at the end of T0, T1 and T2. Intervention participants were interviewed about their experiences at T2.

Results: Completion rates for all self-report items and objective physical activity data were above 85% for the majority of measures. HbA1c data was obtained for 100% of participants, although complete clinical data was available for 63.3% to 63.5% of participants at each data collection time-point. Recruitment and data collection processes were reported to be acceptable to participants and healthcare professionals. Self-reported sedentary behaviour (-2.28, p=0.04, 95% CI=-4.40, -0.16; p = 0.04; $d_{ppc2} = 0.72$) and parent-reported physical health of the child (6.15, p=0.01, 95% CI=1.75, 10.55; p = 0.01; $d_{ppc2} = 0.75$) improved at eight weeks in the intervention group.

Discussion: The trial design was feasible and acceptable to participants and healthcare providers. Intervention engagement was low and technical challenges were evident in both online and activity watch elements, although enjoyment was high among users. Reported outcome improvements were observed at 8 weeks but were not sustained.

Trial registration: ISRCTN 48994721 (prospectively registered).

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Keywords: type 1 diabetes mellitus; physical activity; children; health; feasibility; website; intervention

Themes: Complex interventions, recruitment