

**Title:** Improving Outcomes Among Young Adults with Type 1 Diabetes: The D1 Now Pilot Cluster Randomised Controlled Trial

**Authors:** \*Eimear C Morrissey, PhD (Health Behaviour Change Research Group, School of Psychology, NUI Galway), Molly Byrne, PhD (Health Behaviour Change Research Group, School of Psychology, NUI Galway), Bláthín Casey, PhD (Health Research Institute, University of Limerick), Dympna Casey, PhD (School of Nursing and Midwifery, NUI Galway), Paddy Gillespie, PhD (Health Economics & Policy Analysis Centre, NUI Galway), Anna Hobbins, PhD (Health Economics & Policy Analysis Centre, NUI Galway), Michelle Lowry, MSc (School of Medicine, NUI Galway), Elizabeth McCarthy, PhD (Health Behaviour Change Research Group, School of Psychology, NUI Galway), John Newell, PhD (School of Mathematics, Statistics & Applied Mathematics, NUI Galway), Davood Roshan, PhD (School of Mathematics, Statistics & Applied Mathematics, NUI Galway), Shikha Sharma, MSc (Health Economics & Policy Analysis Centre, NUI Galway), The D1 Now Young Adult Panel, Sean F Dinneen, MD (School of Medicine, NUI Galway)

**Background.** The D1 Now intervention is designed to improve outcomes in young adults living with type 1 diabetes. It consists of three components: an agenda setting tool, an interactive messaging system and a support worker.

**Objective.** To gather and analyse acceptability and feasibility data to allow (1) further refinement of the D1 Now intervention, and (2) determination of the feasibility of evaluating the D1 Now intervention in a future definitive RCT.

**Methods.** A pilot cluster RCT with two intervention arms and a control arm was conducted over 12 months. Quantitative data collection was based on a core outcome set and took place

at baseline and 12 months. Semi-structured interviews with participants took place at 6, 9 and 12 months. Fidelity and health economic costings were also assessed.

**Results.** Four diabetes centres and 57 young adults living with type 1 diabetes took part. 50% of eligible young adults were recruited and total loss to follow up was 12%. Fidelity, as measured on a study delivery checklist, was good but there were three minor processes that were not delivered as intended in the protocol. Overall, the qualitative data demonstrated that the intervention was considered acceptable and feasible, though this differed across intervention components. The agenda setting tool and support worker intervention components were acceptable to both young adults and staff, but views on the interactive messaging system were mixed.

**Conclusions.** Some modifications are required to the D1 Now intervention components and research processes but with these in place progression to a definitive RCT is considered feasible.

**Trial registration.** ISRCTN (ref: ISRCTN74114336).