Supporting insulin initiation in type 2 diabetes in primary care: results of the Stepping Up Pragmatic cluster randomised controlled clinical trial

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Introduction

By 2030, nearly 600 million people globally will have type 2 diabetes, reflecting the significance and urgency in developing effective clinical care innovations. Current UK, European and US guidelines recommend early adoption of insulin to manage glycated hemoglobin (HbA1c) levels below 7%. However, insulin initiation is underutilised, particularly in the primary healthcare setting, where average HbA1c prior to starting insulin is usually 1.5-2.0% above target levels.

Factors delaying insulin initiation include clinician related, systemic barriers, and patient factors. Thus, a trial was conducted to evaluate the "Stepping Up" model of care, empowering primary care practice nurses to integrate insulin initiation as part of standard practice through enhanced knowledge and skills. The model also involved reorientation of specialist registered nurses towards mentorship of practice nurses instead of being the primary care provider. Hence, this study aimed to answer the research question "Does the Stepping Up model of care result in improved insulin administration and HbA1c in patients with Suboptimal HbA1c control in Australian General Practice?". The trial is hypothesised to have improved HbA1c levels amongst patients in intervention armed practices without adversely affecting their emotional well-being.

Methodology

Setting: Australia

Study: To evaluate the effectiveness of the "Stepping Up" model of care as compared to the usual care, a two-arm, non-blinded cluster randomized controlled trial was conducted over 12 months.

Participants: Eligible participants included adults with type 2 diabetes whose HbA1c levels ≥7.5%. They had to be either already prescribed maximum oral treatment within the past 6 months or judged to benefit from taking insulin. Individuals older than 80, already using insulin, or with certain medical conditions were excluded from this study.

Intervention: Practices in the control group followed the normal Australian Type 2 diabetes management guidelines, whereas the intervention group received an in-practice briefing and training session to ensure successful implementation of the "Stepping Up" model of care. Specialised registered nurses with diabetes educator credentials also had a re-orientation of their role, where they focused on mentoring practice nurses rather than providing direct patient care.

Data collection: Participants were given a blood glucose meter and data was uploaded from the meter at 6 and 12 months. Participants were also regularly followed up with clinically to monitor their HbA1c levels at pathology laboratories across the timeframe of the study. Additionally, through interviews conducted at the end of trial, the study also assessed secondary outcomes, such as the change in depressive symptoms, diabetes specific distress and generic health status of the participants.

Data analysis: Mixed effects linear regression was used to determine predictors for continuous outcomes, adjusting for baseline measures and clustering at the practice level.

Results

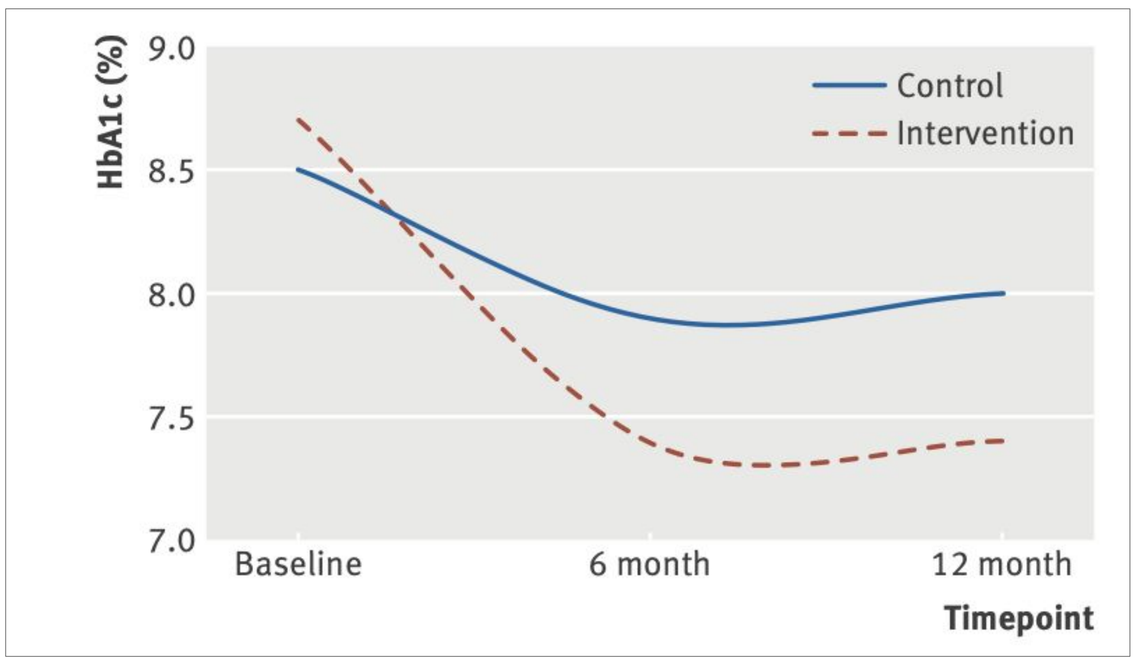

Fig 1. Change in HbA1c as the primary endpoint over 6 and 12 months.

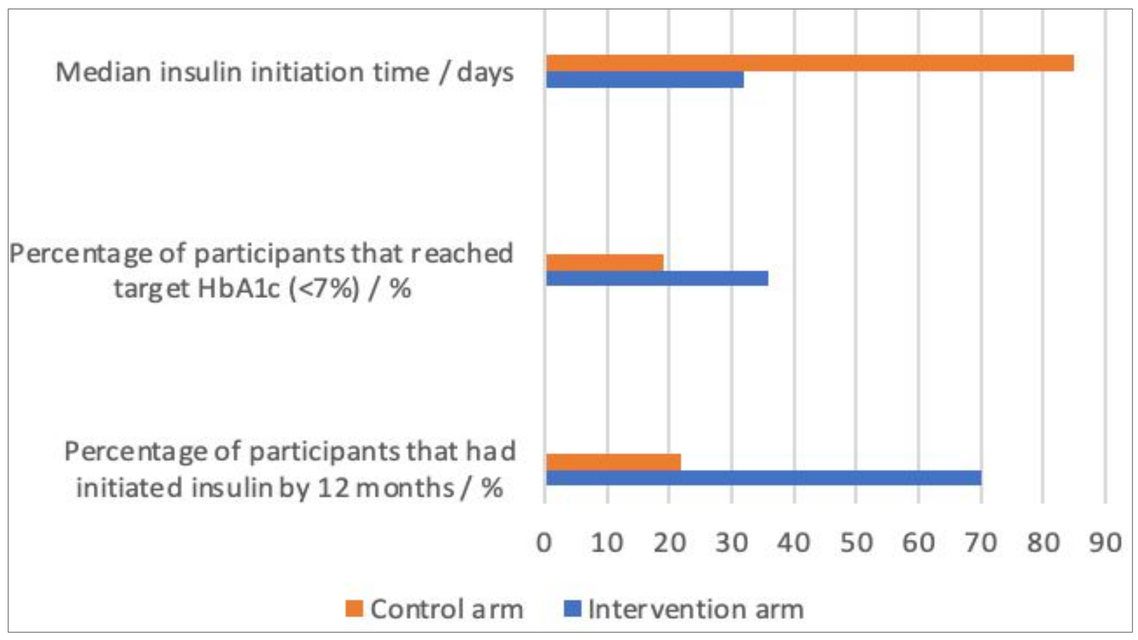

Fig 2. Summary of different secondary endpoints between intervention and control arm

Overall, 224 patients from general practices participated, with an average of 3 patients per practice. At 12 months, the intervention group achieved a significant reduction in HbA1c (mean difference: −0.6%, P<0.001), meeting the primary outcome of an absolute 0.5% reduction compared to controls.

Other secondary endpoints that were assessed include percentage of insulin initiation which was more frequent in the intervention group than control (70% vs. 22%), and median insulin initiation time of 32 vs. 85 days in intervention and control arms respectively (P=0.005). Target HbA1c (≤7%) was reached by 36% of intervention participants versus 19% of control participants (odds ratio 2.2, P=0.02).

Discussion

The "Stepping up" model of care produced a clinically and statistically significant improvement in glycaemia among adults with type 2 diabetes managed in primary care, without deterioration in emotional wellbeing or health status. These results indicate that, with appropriate support and redesign of the practice system, insulin initiation can become part of routine diabetes management in primary care, obviating the need to refer to specialist services with geographical, cost, and accessibility barriers.

Success in the "Stepping Up" model of care can be attributed to it being based completely in the familiar environs of patients' own primary care practices, built on existing relationships and resources (with the practice based practice nurses), and provided an immediate pathway for the GP to delegate this clinical task. This was associated with improved Insulin administration rates and HbA1c.

Trial findings from the "Stepping Up" model of care have implications for the organisation of healthcare and health policy, as well as for clinical practice. The trial findings have emphasised the need for development of the primary care workforce models to reorient the way specialists offer support to primary care teams that include well supported and resourced primary care nurses. In order to ensure timely intervention with insulin in Type 2 Diabetes patients, the "Stepping Up" model of care has the potential to improve outcomes while making better use of scarce healthcare resources. Moving forward, further research can be conducted to assess the sustainability of the "Stepping Up" model of care, ensuring that the benefits of the model are carried on into the long term, further boosting the "Stepping Up" model's suitability to be integrated into primary healthcare.

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