Innovative Medical Technology Overview: Number 008/2017

This IMTO summarises a submission by Andrew Keen and Kirsty MacLennan (both NHS Grampian) regarding the following medical technology. It should be read in conjunction with the accompanying IMTO Review Document, which is an impartial review of the strengths and weaknesses of the evidence submitted to Healthcare Improvement Scotland.

ACT Now!

Technology

ACT Now! is a brief, guided self-help programme aimed at improving both glycaemic control and emotional well-being of people with Type 2 diabetes. ACT Now! is designed for people who have not managed to make changes to key self-management behaviours using standard care and education and/or where anxiety or depression complicates the clinical picture.

ACT Now! is based upon psychological theory and intends to encourage people to live the kinds of lives they want, and uses this, not health itself, as motivation to change health-related behaviours.

The ACT Now! programme offers an additional structured educational tool for the management of Type 2 diabetes. The comparator is therefore routine diabetes care.

Product Performance

A single arm cohort study (n=59) was conducted in a primary care setting in Grampian health board. Two comparisons were made to analyse the outcomes data: a before-and-after comparison within the ACT Now! group and a comparison with a retrospectively collected control group (n=343).

In the before-after comparison, HbA1c declined by 9.3mmol/mol from a baseline mean of 80.3 to 71.0 (p<0.001). The average time between baseline and follow-up was 14.4 months. Statistically significant improvement was also observed for psychological outcomes; mean HADS Anxiety decreased from 5.6 to 4.2 (p=0.001) and mean HADS Depression decreased from 4.5 to 2.6 (p<0.001). In the

Economic considerations

Resource requirements for ACT Now! include: a clinical associate applied psychologist (Band 6), access fee for web materials, patient recruitment materials, staff training costs, printed patient manuals and pedometers. The total cost per patient enrolled in the programme, assuming a single psychologist and recruitment of 170 patients in each service was £275.

An exploratory economic analysis – using the UK Prospective Diabetes Study (UKPDS) outcomes model - was undertaken to gauge the potential life time effects of a reduction in HbA1c levels for the patients that had participated in ACT Now!.

Based on these short term changes in risk
comparison with the historical control group - deemed to have similar characteristics to the ACT Now! group including poorly controlled diabetes at baseline (HbA1c > 61mmol/mol) - the mean change in HbA1c of -9.3 in the active group compared favourably with a reduction in HbA1c of -2.4 (p=0.06) in the control group (median follow-up 12.7 months).

Key limitations with the data presented were the relatively small sample size (n=59) and design of the pilot study. The study focused around an observational design, and self-selection rather than randomisation, which contributes to concerns of bias in the estimated treatment effects.

Despite the promising results summarised here, in order to alleviate concerns surrounding true treatment effects, further research in the form of a randomised controlled trial is desirable.

<table>
<thead>
<tr>
<th>Safety</th>
<th>Organisational and patient issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no known safety issues related to ACT Now!</td>
<td>There is some uncertainty about whether suitable clinical applied associate psychologists or equivalent could be employed to deliver the programme. It is not known if it will be possible to find sufficient staff at the suggested grade if the intervention were rolled-out across other health boards.</td>
</tr>
<tr>
<td></td>
<td>Clinical expert comments noted the positive reports from patients and also highlighted the otherwise unmet need for this patient group (i.e. patients requiring mental health support and/or many years down diabetes pathway).</td>
</tr>
</tbody>
</table>

What is an IMTO?

Innovative Medical Technology Overviews (IMTOs) summarise the evidence relating to an individual technology that has been submitted by the manufacturer of the technology.

The purpose of IMTOs is to provide information that will contribute to local decision-making by NHS health professionals, NHS managers, and procurement colleagues.

IMTOs do not contain recommendations for NHSScotland and should be considered alongside existing guidance applicable to NHSScotland.

Chair
Scottish Health Technologies Group