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The impact of sharing personalised clinical information with people with type 2 diabetes prior to their consultation: A pilot randomised controlled trial

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ABSTRACT

Aim: To assess the impact of sharing personalised clinical information with people with type 2 diabetes prior to their out-patient consultation on patient involvement during the consultation, diabetes self-management self-efficacy and glycaemic control.
Methods: A pilot three-arm randomised controlled trial. The 'intervention booklet' group received a booklet including personalised clinical information, a 'general information booklet' control group received a booklet with no personalised clinical information and a 'usual care' control group received no written information.
Results: 136 people took part. The intervention group were significantly more likely to have shown the booklet to a 'significant other', (48% V 23%, $p < 0.05$), brought the booklet with them to the clinic (85% V 35%, $p < 0.005$) and to refer to the booklet during the consultation (45% V 13%, $p < 0.005$). No significant differences in patient involvement during the consultation, diabetes management self-efficacy or glycaemic control were found between the three groups.
Conclusions: Although participants found it useful to receive their clinical results, no differences were found in the patient outcomes measured.
Practice Implications: Further pilot work on the timing of the intervention, who it is targeted at and what outcomes are measured is warranted before proceeding to a full-scale RCT.

1. Introduction

Successful diabetes management depends on patients' involvement in their care. Self-management, a major determinant of health outcomes [1], involves people gaining confidence in dealing with the medical and emotional management of their condition and engaging in and maintaining new behaviours [2].

Self-efficacy, the belief in one's ability to succeed in a particular situation, is an important factor in the self-management of diabetes [3]. Enhancing self-efficacy has been shown to positively influence long-term glycaemic control. Glycaemic control is strongly associated with a person's future risk of diabetes complications [4] and can be reduced through diet, exercise, losing weight and medications.

Knowledge of one's actual and target HbA1c values is hypothesized to be a prerequisite for effective self-management [5]. Sharing test results with diabetes patients prior to their annual review consultation is welcomed by patients [6] but evidence on the association between knowledge of one's HbA1c and self efficacy and self-care behaviours is conflicting [5,7,8].

Effective communication between the patient and the doctor during a clinical consultation is seen as essential in enabling the patient to self manage [9]. Previous reviews of interventions to improve communication in consultations highlight the absence of rigorous trials [10] and the need to assess the effects of this type of intervention on health outcomes [11].

In Ireland, many people with type 2 diabetes receive most of their diabetes care in a hospital setting, attending an out-patient diabetes clinic once or twice a year. Out-patient diabetes clinics are busy with review consultations on average taking between 10 and 15 min. A previous study conducted in an Irish outpatient setting found that patients who received their test results and targets prior

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to their out-patient consultation were more likely to take the lead in discussing aspects of their diabetes care during the consultation. The study was a non randomised controlled trial and did not measure the impact of this intervention on health outcomes [12].

The Medical Research Council recommend that interventions have a theoretical basis and that pilot studies should be conducted prior to a full evaluation of an intervention [13]. The theoretical basis for our intervention was based on Bandura's self-efficacy theory [14]. We anticipated that providing patients with their clinical results and targets would increase self-efficacy (by understanding their own clinical data) which would influence decision-making about specific behaviours based on their clinical data. As changes in behaviour could be expected to lead to evidence of change on biomedical markers we also examined changes in HbA1c.

Our pilot study, using a similar intervention to the previous Irish outpatient study [12] but with a randomised controlled design. We aimed to measure the effect of sharing test results and targets with patients prior to their outpatient diabetes review consultation on patient engagement during the consultation, on diabetes management self-efficacy six weeks after the consultation, and on glycaemic control at an average of six months after the consultation.

2. Methods

2.1. Design

We conducted a pragmatic pilot randomised controlled trial. Participants were randomised to one of three groups. Both the intervention and 'general information' groups received a booklet at least 48 h prior to their review appointment. The content of the booklet was informed by interviews with patients, doctors and diabetes nurse specialists. Both booklets contained background information on type 2 diabetes, how to prepare for the appointment, what to expect during the consultation and explanations of common tests and measurements usually discussed during a consultation. Those in the intervention group also received a results page in their booklet with participants' most recent results and measurements for HbA1c, cholesterol, blood pressure and body mass index and targets for these (Fig. 1). This page also included the previous two results so that participants could see whether they had improved or not over that period of time. The 'usual care' control group received no written information prior to their consultation.

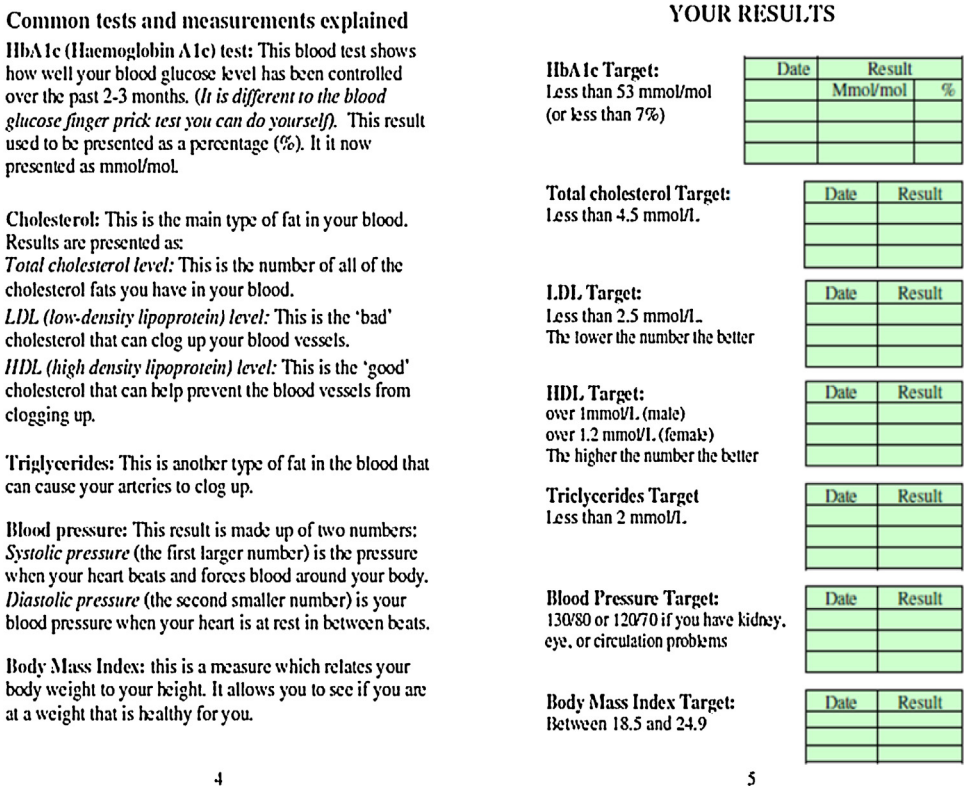
The purpose of the 'the general information' control group was to control for the 'attention' received by the 'active' intervention group, to address potential high drop-out rates in the 'usual care' group who received no information, and to achieve a level of blinding of group allocation from study personnel and participants.

2.2. Setting

The study took place in an outpatient diabetes clinic in a university hospital in the West of Ireland with over 67,000 outpatient consultations annually [15]. Over 70 patients may be registered to attend a half day clinic staffed by five to six doctors. People with type 2 diabetes will usually have a diabetes review consultation once or twice a year and rarely see the same doctor at successive visits because of the annual change over in specialist registrars and junior doctors staffing the clinic. Most patients have their blood tests done prior to their clinic appointment but many will not be aware of their results until they attend the consultation.

2.3. Sample size

Pilot and feasibility randomized controlled trials typically include 30 participants per arm. In this study a total of 50 patients



Common tests and measurements explained

HbA1c (Haemoglobin A1c) test: This blood test shows how well your blood glucose level has been controlled over the past 2-3 months. (*It is different to the blood glucose finger prick test you can do yourself*). This result used to be presented as a percentage (%). It it now presented as mmol/mol.

Cholesterol: This is the main type of fat in your blood. Results are presented as:
Total cholesterol level: This is the number of all of the cholesterol fats you have in your blood.
LDL (low-density lipoprotein) level: This is the 'bad' cholesterol that can clog up your blood vessels.
HDL (high density lipoprotein) level: This is the 'good' cholesterol that can help prevent the blood vessels from clogging up.

Triglycerides: This is another type of fat in the blood that can cause your arteries to clog up.

Blood pressure: This result is made up of two numbers:
Systolic pressure (the first larger number) is the pressure when your heart beats and forces blood around your body.
Diastolic pressure (the second smaller number) is your blood pressure when your heart is at rest in between beats.

Body Mass Index: this is a measure which relates your body weight to your height. It allows you to see if you are at a weight that is healthy for you.

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YOUR RESULTS

HbA1c Target:
Less than 53 mmol/mol
(or less than 7%)

Date	Result	
	Mmol/mol	%

Total cholesterol Target:
Less than 4.5 mmol/l.

Date	Result

LDL Target:
Less than 2.5 mmol/l.
The lower the number the better

Date	Result

HDL Target:
over 1mmol/l. (male)
over 1.2 mmol/l. (female)
The higher the number the better

Date	Result

Triclycerides Target
Less than 2 mmol/l.

Date	Result

Blood Pressure Target:
130/80 or 120/70 if you have kidney, eye, or circulation problems

Date	Result

Body Mass Index Target:
Between 18.5 and 24.9

Date	Result

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Fig. 1. Results page with own clinical data.