Optimal blood pressure control through improved adherence to antihypertensive medication after shared decision making in people with type 2 diabetes (T2DM)

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To improve BP control and health related quality of life by offering a nurse-led patient-centred supportive intervention to people with T2DM who are objectively non-adherent to their antihypertensive medication and/or life style behaviour…

Ethical review	Not approved
Status	Will not start
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON45993

Source
ToetsingOnline

Brief title
INTENSE

Condition

- Diabetic complications

Synonym
type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: European Foundation for the Study in Diabetes

Intervention

Keyword: hypertension, medication adherence, personalised care, type 2 diabetes

Outcome measures

Primary outcome

The difference in blood pressure between groups after 12 months.

The effect of a measurement of the antihypertensive serum level to objectify

adherence to medication on the blood pressure after 12 months

Secondary outcome

What is the effect of a theory driven nurse-led patient-centred approach,

including a decision aid for hypertensive, non-adherent individuals with T2DM

and uncontrolled BP on:

1. Body weight

2. Number of smokers that quit smoking

3. adherence to physical exercise guidelines

4. adherence to nutrition guidelines (salt, vegetable, alcohol intake)

5. BP and the proportion of people that achieve their personalised treatment

target based on SDM;

6. Antihypertensive medication adherence;

7. Reasons for non-adherence

8. Prescribed medication;

9. Beliefs about medication and Illness perceptions;

10. Health related quality of life;

11. Health related costs (cost-effectiveness).

12. Number of referrals to secondary care

Study description

Background summary

More than 75% of people with type 2 diabetes mellitus (T2DM) have an elevated blood pressure (BP). Tight BP control decreases their risk of micro- and macrovascular complications and cardiovascular death. To achieve good BP control, medication adherence is crucial and multiple drug therapy often unavoidable. However, polypharmacy, (assumed) adverse effects and suboptimal health care provider-patient communication hamper adherence to antihypertensive medication. At least 30% of all people with T2DM have a BP above target. Therefore people*s beliefs about medications* effectiveness and adverse effects should be discussed during diabetes monitoring visits. Guidelines advocate discussing medication adherence and shared decision making, but they do not provide an approach for this. We design and assess a practical stepwise personalised approach to improve BP control in people with T2DM.

Study objective

To improve BP control and health related quality of life by offering a nurse-led patient-centred supportive intervention to people with T2DM who are objectively non-adherent to their antihypertensive medication and/or life style behaviour influencing bloodpressure

Study design

Cluster randomised controlled trial (RCT) with 3 trial arms:
1: intervention group 1: blood test + results + intervention
2: intervention group 2: blood test + results + care-as-usual
3. control group: blood test, results after the trial period + care-as-usual

Intervention

After inclusion a bloodtest will be performed at T=0 months and T= 12 months, for the measurement of the serum antihypertensive level, to objectify medication non-adherence. In 2 trial arms, analysis will be performed immediately, and the results will be announced to the patient's physician and the patient. In the care-as-usual trial arm, blood samples will be stored, and

analysis will be performed and results will be announced after the trial period (12 months)

The intervention exists of three nurse-led sessions during 6 months, during the regular diabetes consultations, in close collaboration with the general practitioner or internist. Training of the nurses will focus on illness perceptions, medication use, life style behaviour, socio-economic factors influencing blood pressure and health behaviour. By using a decision aid that visualizes the benefits and harms of bloodpressure control, shared decisions and targets will be made on bloodpressre, related lifestyle changes and/or prescribed medication. Patients wil be trained to improve their health behaviour based on these targets.
Questionnaires concerning adherence perceptions, medication use, life style behaviour, qualitiy of life wil be recorded. Blood pressure will be monitored using a 30 minute blood pressure measurement.

Parallel to the intervention group, the two control arms with refractoy hypertension will be asked to fill in the same questionnaires as the intervention groups. Blood pressure will be monitored using the 30 minute measurement. These groups recieve care as usual.

Study burden and risks

We will measure adherence at baseline and 12 months after formal inclusion. We will determine adherence objectively from plasma samples (see preliminary results for details) and subjectively by the validated Medication Adherence Report Scale 5 (MARS-5). Other measurements (questionnaires: physical activity and salt/ alcohol intake (self-report) BIPQ (9 items); BMQ (19 items); WHO-5 (5 items); EQ-5D/VAS (6 items)) will take place in all participants at baseline, 6 months and 12 months after the baseline visit. Other data will be extracted from the patient medical records. In total three sessions of patient-centred support by a trained nurse will be provided during 6 months. These sessions are provided during the care-as-usual consultation moments in an independent health center.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adults (>18 years) with T2DM AND
2. BP >140/90 mm Hg (people * 80 years) or
> 160/90 mmHg (people > 80 years, based on Dutch guidelines), measured during the last-check up at the general practice/ endocrinologist using a 30-minute bloodpressure monitor.
AND
3. use of three adequately dosed antihypertensive medications, including a diuretic during at least the past 3 months

Exclusion criteria

1. type 1 diabetes;
2. eGFR < 30 ml/min;
3. a history of alcoholism or drug abuse;
4. dementia or major psychiatric disorder that is likely to invalidate informed consent (IC), or limit the ability of the individual to comply with the protocol requirements.
5. Unwillingness to provide a written informed consent.
6. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	264
Type:	Anticipated

Ethics review

Not approved

Date:	31-12-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68122.098.18