Danish Evaluation of Your Heart Forecast (DANY) - Study Protocol for a Randomised Controlled Trial on an Interactive Risk-communication Tool aimed at improving High Blood Pressure Patients' adherence.

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Study protocol

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Abstract

Background To improve communication of risk messages, they must be communicated in a way that is understandable and relevant to the patient. Communicating risk of cardio-vascular-disease is a complex and individualised task, since the risk itself is a combination of multiple personal risk factors. Raised blood pressure is but one of these risk factors. In Denmark, one third of hypertensive patients are adequately treated, with regards to national guidelines. One reason for this meagre status is low treatment adherence, and tools with documented effects for increasing patient adherence are limited. Our objective is to evaluate the effect of a personalised, interactive and dynamic risk-assessment and risk-communication tool: “Your Heart Forecast” on blood pressure control, primary non-compliance, health literacy and patient empowerment.Methods Cluster-randomised controlled trial in general practice. Effect measures are adherence, blood pressure, lipid levels and empowerment at inclusion and after 6 and 12 months. To identify other benefits or possible adverse effects of the intervention, qualitative interviews will be conducted with a subgroup of patients. Discussion The investigators will explore effects of Your Heart Forecast on patients’ health literacy, adherence, empowerment and blood pressure control. The DANish evaluation of Your heart forecast (DANY) project will be the first to rigorously evaluate effects of YHF in Denmark and to link adherence of hypertensive patients exposed to Your Heart Forecast with the national databases of prescriptions and health services provided.

Background

To improve communication of risk messages, they must be communicated in a way that is understandable and perceived relevant to the patients’ personal life and health. Every individual has its own beliefs, values and understanding, as well as social and psychological background. Therefore, communication tools must be personalised and easy to understand. It is important to bear in mind when designing communication tools, that close to half of the European population has a low degree of health literacy (1), which is associated with poor health outcomes, low self-management and underestimation of personal Cardiovascular Disease (CVD) risk(2). Since the risk of CVD is the product of a complex combination of multiple individual risk factors, there is a need for communicating complex information in an easy understandable way. Several tools for calculating and communicating CVD risk has been developed, but rigorous testing of their communicative effects is sparse.

Adherence is generally low for preventive interventions addressing CVD risk(3). Most patients do not feel unwell despite their diagnosis of hypertension or hypercholesterolaemia, and combined with an underestimation of their personal risk, this might be the reason for low adherence to preventive treatment.

In Denmark, general practitioners (GPs) are encouraged by clinical guidelines to conduct an annual blood pressure control assessment for patients with hypertension in order to reach guideline-described levels of blood pressure and to reduce other known CVD risk factors as well (4–6). The annual blood pressure control assessment represents a unique and regular opportunity for the GPs to motivate their patients to

achieve healthier lifestyles and better treatment adherence. However, despite all good intentions, 7 out of 10 Danish patients diagnosed with hypertension have inadequately controlled blood pressure(7,8).

Inadequately controlled blood pressure is associated with a increased risk of CVD, and more frequent contacts with GPs. Intention to change behaviour is related to the patients' perception of risk(9). Consequently, better ways for GPs to communicate CVD risks and motivate patients for risk reducing strategies are warranted. Efficient communication requires information to be presented in formats that encourage decision makers, i.e. patients, to automatically extract specific meanings or overall messages(10). Use of graphical illustrations with distinct features has previously been shown to be an effective and user-friendly tool to communicate risk, especially to people with limited health literacy(2,10,11). A visual decision aid could be a way to improve the blood pressure consultations and to assure that GPs are supported to provide patients with the relevant information. It is suggested that using a decision aid will also systematise the consultation and make it more reproducible(12).

The present study will use the internet-based risk communication tool Your Heart Forecast (YHF) to evaluate, whether it can influence patients' understanding of risk and treatment adherence. This will be done paying special attention to patients' blood pressure, lipid levels, empowerment and health literacy. The rationale behind the tool is to help improve patient-doctor interaction and communication so that the patient can gain an improved understanding of his/her CVD risk, and the modifiability of risk. Patients with hypertension have been chosen as a case study, since high blood pressure is one of the main modifiable risk factors for CVD, as opposed to i.e. age, gender, ethnicity and family history.

YHF is a risk-communication tool, which communicates CVD risks as personalised, interactive and dynamic visual graphs. Following input from personal health related data, the GP can, by using YHF, interactively guide the patient through:

- Their currently predicted 5-year absolute CVD risk
- The age at which they would achieve their currently predicted CVD risk if they had ideal/achievable risk factor control (the heart age)
- Their predicted CVD risk as they get older (the heart forecast)
- Their future CVD risk if their current risk factors are improved.

To succeed in behavioural changes, the patient can be helped in several ways in a setting like general practice. From the perspectives of the Transtheoretical theory/Stages of Change theory(13) and the Information-Motivation-Behavioural Skills theory(13) the present intervention helps patients in several ways as follows. YHF gives the information of CVD risk in a new way and at the same time offers a motivation as it immediately and visually shows the number of years you can add before reaching a condition where pharmaceutical treatment is highly recommended. As such, YHF presents the information leg as well as the motivation leg from the Motivation-Behavioural Skills theory, which together is expected to strengthen the patient's behavioural skills and to add to the likelihood of sustaining a behavioural change.

As it has previously been demonstrated that single event interventions do not have an effect if not followed up, YHF will be introduced in a package deal. YHF will function as the primary intervention and repeated reminders via e-mail will be the secondary component. Patients in the intervention group will, after the consultation with the GP, receive emails every other week, as part of a general health literacy educational program.

The second part of our planned intervention, the reminding e-mail program, aims at the action and maintenance stages regarding the Transtheoretical theory(14). Every other week, patients in the intervention group, will receive an email with a piece of advice on how to live healthier. In the same email, a reminder and a link are inserted, through which the patient can play back the information given at the blood pressure consultation at the GP, using YHF. The email-program offers a possibility to boost the patients' motivation and by that support the ongoing behavioural change.

Methods/design

Aim

The aim is to evaluate the effect of using the YHF visual communication tool on changes in blood pressure and adherence to CVD preventive medications. Further, by means of questionnaires, the aim is to study whether changes in health-literacy, adherence, patient empowerment and risk communication are associated with changes in blood pressure, lipid levels and/or life style choices. By means of qualitative interviews, it will be investigated whether the use of the program heighten motivation, increases awareness of risk or creates unwarranted effects like causing the patients to be anxious.

Research question

Primary research question:

- Will the introduction of YHF during an annual blood pressure control consultation lead to improved general health literacy, improved medication adherence and empowerment after 12 months?

Secondary research questions:

1. Will blood pressure be reduced among patients in the intervention group compared to the control group after 12 months?
2. Will lower health literacy and/or low empowerment at baseline be associated with higher blood pressure at baseline?
3. Will health literacy and/or empowerment be improved after 6 and/or 12 months among patients enrolled in the intervention group?
4. Will increased health literacy and/or empowerment be associated with healthier lifestyle including diet, exercise and smoking habits after 12 months?

5. Will there be subjective feelings of increased motivation or sickening after introducing the intervention?
6. Will CVD risk be lower among patients in the intervention group compared to the control group after 12 months?

Clinical relevance

- Low medication adherence is a significant health, time and cost consuming challenge for patients with increased blood pressure as well as for their GPs.
- The study is not only relevant for the individual patient, but due to the very high prevalence of increased blood pressure, also of significant societal relevance.
- The study will address this clinically relevant challenge through improved risk communication and efforts to improve health literacy.
- Increased health literacy will most likely lead to fewer visits to the GP, better adherence, lower degree of complications, and thus, higher quality of life for the patient and fewer health costs for the society.

Trial Design

This study will use a mixed methods approach with a combination of a randomised controlled trial (RCT) and qualitative semi-structured interviews. The protocol has been developed using the SPIRIT checklist as guideline.

Participating general practices will be cluster randomized into two groups, an intervention and a control group. The randomization will be done by using REDCap's randomization tool. Two general practices will function as pilot practices and be enrolled as if they were intervention practices. In these 2 practices patients will be assessed 3-6 months before the project practices. A subgroup Q, of 5-15 patients from the pilot group, will be selected for qualitative interviews.

GPs in the control group, will not be introduced to YHF and will follow their patients in the blood pressure control program as usual.

Study population

Participants

All general practices in the Region of Southern Denmark will receive a postally distributed, written invitation to an information meeting about the RCT. Practices not attending the meetings will in following inclusion rounds, be offered an introduction to the trial via video meetings. 30 GPs of those willing to participate, will, with due respect for geographical location and practice type, be representatively selected for participation.

Both incident and prevalent hypertensive patients will be included within an inclusion period of 6-12 months.

Sample size

Sample size calculation is based on blood pressure as primary outcome. For a two-sample pooled *t* test of a normal mean difference with a two-sided significance level of 0.05, a sample size of 120 participants per group is required. This is to obtain a power of at least 90%, to detect a difference of 5 mmHg between the means at baseline and after 1 year. To adjust for expected drop-outs, 30 participants will be added per group and at least 300 patients will be enrolled in the trial. To account for cluster-effects when randomising on practice level, the sample size will be further increased by 10-15% to reach 340 patients. More participants will be needed for subgroup analyses on sociodemographic and therefore, the aim is to reach a total of 600 participating patients. The pilot practices will provide information regarding the prevalence of patients with inadequately controlled blood pressure willing to participate, as well as more specific knowledge on the needed number of practices included, making the final sample size calculation uncertain at this point.

Randomisation

Participating GPs will be randomly divided in to two groups A and B, using the randomisation tool built in to REDCap. They will be given Trial General Practice Numbers (TGN) from A01-A15 (group A) and B01-B15 (group B).

Participants will be given Trial Participant Numbers (TPNs). TPNs will be generated by PREDICT (the software behind Your Heart Forecast) when patients are included and will be given consecutively starting from 0001. The number will be given a prefix A or B depending on which group (intervention or control) the participant's general practice belongs to. Thus, the sequence of TPNs can vary in prefixes but will consist of unique 4-digit numbers (i.e. B0001, B0002, A0003, B0004, A0005, A0006, A0007… …). With this method of labelling TPNs and TGNs, there is room for adjustment if the number of participants/GPs ends up being either smaller or greater than the expected 640/32 in total.

Subgroup Q will be 5-15 participants chosen deliberately from the pilot group, to ensure it represents the intervention group for use in the qualitative interviews.

Inclusion criteria for general practices

1. To ensure comparability to usual care, all the included general practices must use their own routine method to take blood samples, ECG etc., prior to annual blood pressure control consultations. All general practices in Denmark are supposed to follow a national quality guideline and take part in continuing education. This means that the standard routine methods vary only little across the country

2. To ensure equal quality, all general practices must measure blood pressure using an ambulatory blood pressure device under standard conditions.

3. To ensure comparability to usual care, inclusion and subsequent intervention must be in connection to a planned blood pressure control consultation, as part of the standard blood pressure control program (either at the time of diagnosis or as a planned annually control).

These criteria are controlled when the first author visits the practices in the start-up-faze (see chapter: “Practical procedures”).

Inclusion criteria for patients

1. All patients must understand and read Danish and must be cognitively well functioning (be able to understand the trial information given, and thus make a decision on whether to participate on acceptable grounds).
2. The patients must have Internet access, have an email address and read their emails on regular basis (at least once a week).
3. Patients must give informed consent prior to inclusion.
4. All included patients must be diagnosed with hypertension and participate in blood pressure control consultations with their GP at least once a year.
5. Both patients with known hypertension and those newly discovered are accepted into the trial.
6. Age from 35 to 75 years.
7. Males and females are included.
8. Comorbidity is allowed with a few exceptions (see exclusion criteria).

Exclusion criteria for patients

1. If the patient during the trial, no longer fulfils inclusion criteria 1 and/or 2, they are excluded from the trial.
2. If the patient during the trial develops prolonged illness so severe that treatment of hypertension is no longer a priority, he/she will be excluded.
3. Patients with blood pressure above 170/100 are excluded, as these patients should receive intensive blood pressure treatment regardless of their predicted CVD risk or heart age.
4.
5. Very high cholesterol (TCL or TCL/HDL 8 or over).
6. Genetic lipid disorders.
7. If the patient is diabetic AND has a complicating kidney disease.
8. Known problems with arteries to the legs defined as:
   a. Clinical symptoms of claudication
   b. Diminished foot pulses
   c. Carotid bruits

d. Radiological evidence of atherosclerotic arterial disease
e. Prior surgery /percutaneous interventions

9. Prior stroke or mini-stroke (TIA).
10. Angina, prior AMI or heart related operation.

Practical procedure

General practices will be actively involved in the RCT as follows (see trial flow chart – figure 1). All participating practices will receive a one-hour introduction to the project in their own clinic, conveyed by the first author, AEJ, and the staff members will at this time also receive relevant documents for further distribution to patients. At the introduction, the first author will assist the GP in drawing a list from the statistics module of their electronic patient journal. The list will show patients with the hypertension diagnoses K85, K86 and K87 and it will be sorted by CPR-number (central personal register) starting with 1st of January.

After identifying the list of patients from the statistics module, the practice will review the patients with regards to the inclusion/exclusion criteria. After exclusion, an invitational letter will be sent out to the first 25 of the remaining patients on the list. The invitation will contain a specific appointment for the patient, scheduled for the inclusion consultation with their GP. The invited patients can then opt out or show up at the appointment and receive the oral and written trial participant information. The inclusion consultation will be planned prior to the patients expected annual blood pressure consultation and will be planned so they can get blood samples taken at the same time. Thereby patients will not need to go to the practice more times than usual, but the practice will need to conduct an extra GP consultation to give trial information. The practice will be compensated for this extra consultation.

A few days after the inclusion consultation, the participant will receive an email with a link to a questionnaire, which must be completed before the subsequent appointment with the GP. The first page of the questionnaire will be the informed consent form. If the patient answers no to the informed consent, further access to the questionnaire will be closed and the patient will be excluded from the trial.

The GP responsible for the following blood pressure control consultation will ensure that the questionnaire is filled out by the patient. GPs of the intervention group must subsequently guide their patient through YHF on their computer, uploading this individual patient´s data.

With the large number of patients with known hypertension and the compressed method of inclusion, it is expected that GPs will have enough use of the program Your Heart Forecast, to maintain the skills and knowledge to use the program, which they will be taught by the research group before start of the project.

The RCT will consist of a 12-month intervention period, except for participants in subgroup Q who will be interviewed 6 months after enrolment (t_6) and subsequently excluded. Follow-up for all other patients will

happen at the next annual blood pressure control consultation (t_{12}) approximately 12 months after registration of baseline data (t_0).

The intervention group will receive an educational e-mail, which also includes a reminder of the project and YHF, every 2 weeks. The first e-mail is sent out approximately 2 weeks after the initial blood pressure control consultation. The last e-mail is sent out 2 weeks prior to the expected 1 year follow up blood pressure control consultation. The e-mails' health educational content will reflect available information from the Danish Heart Association's web page (www.hjerteforeningen.dk).

The GPs are asked to make sure that blood pressures are measured as a standard ambulatory blood pressure just prior to the annual blood pressure control (t_{12}).

Data collection:

Recruitment will take place from summer 2019 until the intended sample size is reached, presumably within 12 months. The RCT is expected to be completed during 2020.

Baseline data will be collected at recruitment, via the patient questionnaires and medical records.

The questionnaire (q_1) will include questions to evaluate socioeconomic and sociodemographic variables, baseline health literacy, risk perception and self-efficacy (PAM-13(15)), smoking status, comorbidity and medication.

The second patient questionnaire (q_2) is very short and will be sent out by email approximately 2 weeks after the first questionnaire and the informed consent has reached the research group. This questionnaire will focus on whether the patient was surprised about the risk score, if any changes in the medication were made and how the general experience of the YHF is. In this email, the intervention group will be informed that they have been selected to receive an email every second week with information about general health literacy, CVD risks and advice regarding risk reduction.

Six months after enrolment (t_6) participants will be asked to answer the first questionnaire (q1) again.

Data regarding blood pressure will be obtained through questionnaires at baseline and after the first annual blood pressure control (t_{12}), where blood pressure should also be measured as an ambulatory blood pressure. Data regarding number and content of contacts to the GP will be obtained from the patient´s medical records and the affiliated accounting system including prescription databases for estimating compliance. All telephone consultations, email consultations, clinic consultations and home visits are registered. Contacts from three years prior to the intervention and up until two years after, will be obtained.

Patients in the intervention group will receive their personal profile in the YHF to make it possible for them to access and use the program at home in between the blood pressure consultations at their GP. To gain access to their profile from home they shall use a personal link sent by email at the end of the blood pressure consultation with their GP. All data entered in YHF will be stored in accordance with Danish law by the software provider, with whom a data management agreement has been made.

Base-line measurements of health literacy, risk perception and PAM-13 will be used (in conjunction with socioeconomic and sociodemographic variables) to identify sub-groups of participants. Qualitative data will be obtained via semi-structured interviews, transcribed and analysed with systematic text condensation. The qualitative interviews will seek to shed light on possible explanations for the hypothesized effects on self-management, life style choices, blood pressure and contacts to the GP. If possible, the PhD student will personally make all interviews and transcriptions. In case of time constraints, an assistant will carry out part of the qualitative data collection and transcriptions.

Outcome measures and statistical analysis:

For continuous outcomes, i.e. blood pressure and number of GP contacts, linear regression analysis of mean changes from baseline will be carried out. Ordinal regression and multinomial regression will be used for ordered and categorical outcomes i.e. PAM13 score. Adjustments for baseline values will be made. An intention-to-treat analysis will be applied. Subgroup analyses to identify groups that especially benefit from the intervention will be performed.

Discussion

Despite the variety of CVD risk communication tools that exists, adherence to medications remains low for hypertensive patients. There is a world-wide focus on improving adherence and/or compliance, but often there is a lack of rigorous testing of the tools' communicative qualities. There is much to be gained by developing adherence enhancing interventions, maybe even more than by producing new drugs. YHF is a well-used risk communication tool in New Zealand, but it has not been rigorously evaluated there. Since the DANY project will be the first to test YHF in Denmark, it will also be the first to link adherence of hypertensive patients with the YHF and with national databases. It is uncertain to what extent health literacy and empowerment influences patients' adherence, but both will be important indicators in the DANY-project.

Limitations

It is not possible to control how the GPs act in their own practices. This leaves room for some differences in procedures and information given. This can, however, also be seen as a strength, because the usual care given to the patients by their GP will not be changed. The message drawn from the tool will not be precisely alike for all GPs, but this diversity will reflect real life and that is the goal of the trial – to test whether YHF works in a real life setting of general practice.

It cannot be controlled whether patients take the medications they pick up at the pharmacy. The prescription database should, however, be a reliable reflection of patients' intake of medicine, since patients presumably take the medications they buy.

The randomisation will be done at GP level instead of patient level. It cannot be expected of a GP to use the YHF with one patient and not be influenced by the process, when the next patient comes. GPs will always intend to give their patients the best treatment they can, but the potential for a spill over effect is accounted for, by choosing the cluster randomisation process.

The inclusion of GPs will be done by handing out information about the trial and then leaving it up to the GP whether they wish to participate. This might lead to a selection bias, as those willing to participate might have greater interest in hypertension than the GPs not interested in participating. On the other hand, this possible selection bias might give an underestimation of any positive result, if such is to be found, since the participating GPs are possibly already good at treating hypertension.

Use of ambulatory blood pressure measurements will give higher values of blood pressure compared to home blood pressure measurements, but this will only result in a stochastic variance and therefore not influence the outcomes of the trial.

All communication to patients between the consultations, is done by email. As reading emails regularly, serves as an inclusion criterion, it will potentially exclude some patients with hypertension from participating in the trial. However, given that Denmark has one of the highest levels of internet coverage of its population, and that all official communication from public institutions to citizens, are already sent electronically, it does not seem like a significant challenge.

Clinical implications/perspectives

It is expected that using Your Heart Forecast will improve health literacy and patient empowerment, increase medication adherence, and lower patients' blood pressure. Further, socio-demography is expected to have a significant impact on these outcomes. If the introduction of Your Heart Forecast is shown to significantly improve patient adherence or reduce hypertension, it should be implemented on a larger scale. By using YHF, focus is moved towards patients' total CVD risk instead of just hypertension.

The wider perspective of the present trial is the generic potential, that improved risk communication through a dynamic and interactive communication tool, can change not only empowerment, understanding and relevant health outcomes for CVD, but also for other diseases.

Trial Status

Current protocol is: *version 2.5, August 2019.*

The trial began the pilot phase as of March 2019 and the first recruitment consultations for project participants where done in June 2019. Recruitment is planned to be completed in March 2020.

Abbreviations

CVD = Cardio Vascular Disease

GP = General Practitioner

RCT = Randomised Controlled Trial

SDU = University of Southern Denmark

TGN = Trial General Practice Number

TPN = Trial Participant Number

YHF = Your Heart Forecast

Declarations

Approvals:

This study is a non-pharmacological study and classified by The Regional Committees on Health Research Ethics for Southern Denmark as not notifiable (Project-ID: S-20170206). The study is reported to and approved by the Danish Data Protecting Agency through the legal office at SDU. Approval from Danish Health Authority is needed for access to data from national databases. Informed consent from participants will be obtained at inclusion and renewed at 6 and 12 months. The informed consent grants access to the patient's medical file at the GP.

Consent for publication: *Not applicable.*

Availability of data and material:

Access to the final dataset will be limited to the authors' research groups.

Results will be published in peer reviewed journals as well as at conferences and meeting for participating general practitioners. Authorships will follow the Vancouver declaration.

Competing interests:

The authors state that they have no competing interests.

Funding:

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Authors' contributions

First and last author are the main contributors, but all authors have taken part in developing both study protocol and manuscript. All authors have read and approved the final manuscript.

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Authors information

Professor Rod Jackson has been the leader of the research team in New Zealand which has explored the use of YHF and results thereof in New Zealand, since the creation of the program. As such he has thorough knowledge of the YHF and the algorithms behind the prediction model.

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Additional Files

Additional file 1: "DANY_flowchart_for_protocol.pdf", is figure 2.

Additional file 2: ".S-201702006 English version - Health Research Ethics committee", is the letter of decision from **The Regional Committees on Health Research Ethics for Southern Denmark.**

Additional file 3: ".RIO statements and translation.pdf", is the letter of decision from the **legal office at The University of Southern Denmark.**

Additional file 4: "spirit checklist-filled-out.pdf", is the filled-out SPIRIT check-list for the protocol.

Additional file 5: "DANY_Questionnaire_q1.pdf", is the first questionnaire the participants receive and contains the informed consent as the first question. The questionnaire is in Danish.

Additional file 6: “DANY_patient_information.pdf”, is the material that every patient is handed in hard copy before inclusion. The material is in Danish.

Figures

Figure 1 (SPIRIT figure)	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT	*3 months before inclusion*	*1 week before inclusion*	*Inclusion consultation*	*1-2 days after inclusion consultation*	*Annual Blood pressure consultation at GP*	*1 week after BP consultation*	*6 months after inclusion*	*1 year follow up blood pressure consultation*
ENROLMENT:								
Eligibility screening	X							
Randomization of general practices		X						
Oral and written trial information			X					
Informed consent				X			X	X
INTERVENTIONS:								
Questionnaire q1				X			X	X
Use of Your Heart Forecast					X —	—	—	X
Biweekly email follow ups					—	—	—	—
Questionnaire q2						X		
Interviews							X	
ASSESSMENTS:								
Sociodemographic				X			X	X
PAM13				X			X	X
Height and weight				X			X	X
Blood pressure				X				X
Lipid levels				X				X
Experience of intervention						X	X	
User frequency of YHF								X
Number of contacts to GP before and during DANY								X

Figure 1

SPIRIT Figure

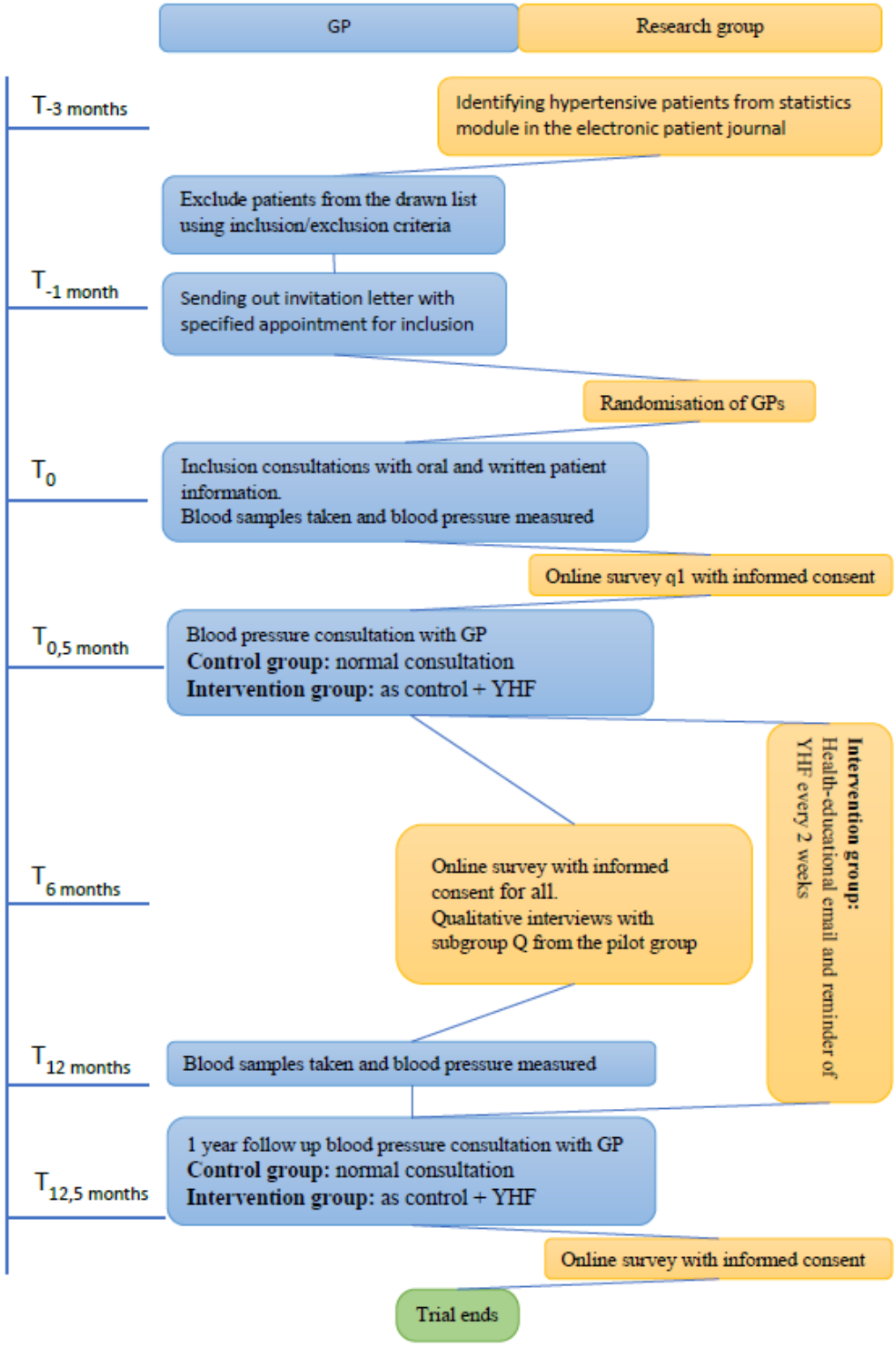

Figure 2

Flowchart for protocol

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- supplement1.pdf
- supplement2.pdf
- supplement3.pdf
- supplement4.pdf
- supplement5.pdf
- supplement6.pdf