Evidence-based development and initial evaluation of a facilitated patient self management strategy intervention for hypertension

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McMaster University HEALTH SCIENCES

Department of Family Medicine

STONECHURCH FAMILY HEALTH CENTRE

MyBP Hypertension Self-Management

MyBP Team

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BACKGROUND

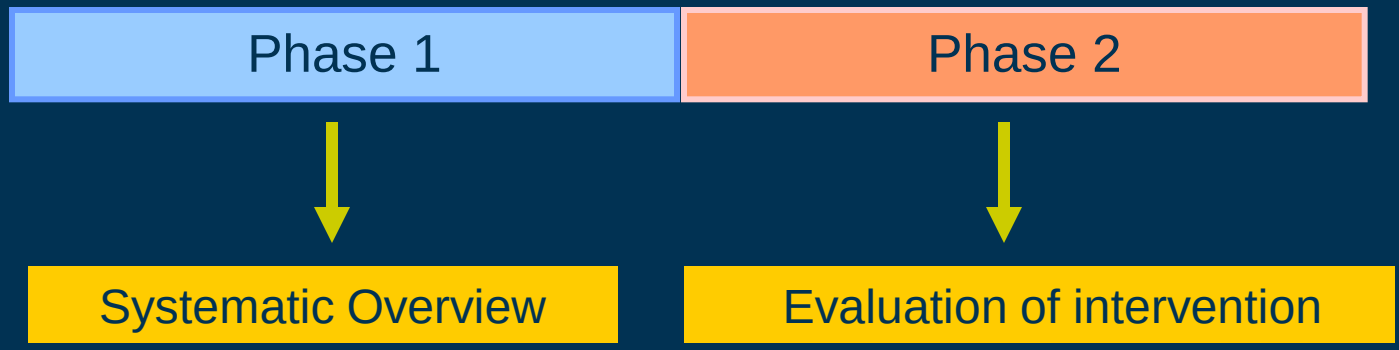
- Priority in primary care: Strategies for prevention and management of chronic disease
- Improved health outcomes observed when[1]:
  - Engage patients in self-management activities
  - Provide support from care providers
- Hypertension – important modifiable risk factor[2]
- Self-management resulted in ↓ blood pressure[1]
- Web-based resources have potential to
  - Overcome barriers to optimal management
  - Deliver health information and support

1. Chodosh J et al. *Ann Internal Med* 2005;143:427-38.
2. Patel R et al. *J Human Hypertension* 2006; 1-9.

OBJECTIVES

- To determine the effectiveness of web-based patient self-management programs for hypertension
- Identify components of effective interventions
- Identify how components work together as a system of care to assist design of future programs
- Test an evidence-based intervention

‘MyBP’ Hypertension Self-Management Program



Phase 1: Systematic Overview

METHODS

Search strategy

- 1998-2008
- Medline, EMBASE and CINAHL
- Manual search of reference lists
- PubMed *Related Articles* feature

METHODS

Selection of trials

- Published in English
- RCT or prospective cohort with a concurrent control
- Community dwelling adults in primary care
- Web-centred intervention focused on ↓ risk for htn or treating htn
- BP a target, measured outcome
- Control group received usual care
- Exclusion: one-way transmission of data

- Two independent raters (differences adjudicated by a third rater)

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METHODS

Data abstraction

- Structured data extraction forms
- Two independent raters (differences adjudicated by a third rater)
- *A priori* outcomes:
  - SBP, DBP, HRQoL, patient satisfaction, ER visits, primary care visits, specialist visits, mortality, use of system (logins/posts/messages/uploads), and patient self-management (eg, patient perspectives).

METHODS

- Analysis
  - Data summarized and combined qualitatively

RESULTS

3845 citations identified → 9 RCTs included

Coding agreement between raters for citations		
	% agreement	kappa
Title	93.5	0.81
Abstract	81.2	0.38
Full text	96.1	0.78

RESULTS

Study Characteristics

- 8 of 9 studies conducted in North America (2 in Canada)
- 5 conducted in primary care setting; 4 conducted out of hospitals
- Length of intervention: 12 weeks to 1 year
- 2 with hypertension as explicit inclusion criterion

RESULTS

Study Quality

- All included studies were RCTs (2 cluster RCTs)
- 5 trials reported allocation method
- 5 trials incorporated some blinding
- 6 trials used intention-to-treat analysis
- 7 trials reported reasons for participant withdrawal
  - 1 did not have withdrawals; 1 still ongoing
- Completeness of follow-up: 71.4% to 100%, average: 90.3%

RESULTS

Patient characteristics

- Sample size: 15 to 1665 (mean 435.6, median 104)
- Proportion of female participants (per group): 0% to 63.5%
- Average age (per group): 55±12 years to ~70 years
- Baseline SBP (per group): 120±7 mmHg to 153.1±13.2 mmHg
- Baseline DBP (per group): 76±7 mmHg to 91.2±8.1 mmHg
- 8 of 9 studies reported either weight or BMI
  - majority of trial participants were overweight or obese

RESULTS

Effects of the Intervention

- Blood pressure
  - 5 of 9 trials: significant ↓ mean SBP with intervention:
    -2.86 mmHg to -14.2 mmHg
  - 2 trials: significant ↓ mean DBP with intervention
    -1.54 mmHg; -7.0 mmHg

- Other outcomes of interest
  - Only 2 trials measured > 2 of predefined outcomes of interest

Intervention components	n =5
Education/materials	**5**
Online group education	1
Standard group education	0
Personal coach/support	2
Online bulletin board	1
Electronic reminders	1
Entry of personal data	3
Self-monitoring of BP	**5**
Entry/recording of BP	**5**
Self-monitoring of other htn/CV-related parameters	**4**
Entry/recording of other htn/CV-related parameters	**4**
Other self-care activities	3
Use of online personal health record	3
Secure electronic messaging with providers	**4**
BP results shared with provider	2
Medication list	2
Patient-specific recommendations	**5**
Action plan	2

DISCUSSION

Moderate effect on lowering SBP for successful interventions.

Four trials did not show decreases in SBP:

- Zutz et al (2007):
  - BP well-controlled at baseline (121 mmHg and 123 mmHg)
  - Small sample size (n=15)
  - Short intervention period (12 weeks)
- Southard et al (2003): due to the population studied?
  - Patients with cardiovascular disease (dx of CHD, CHF or both)
- Verheidjen et al (2004): intervention targeted dietary changes, no self- / home monitoring of BP
- Madsen et al (2008): significant ↓ in daytime systolic ABPM from baseline for both intervention and control groups

DISCUSSION

- Web-based self-management of BP appears to an effective strategy for ↓ SBP (unclear for DBP)
- Numerous types of components tested within complex interventions. Components of successful interventions:
  - Provision of education / materials
  - Self-monitoring and entry of BP
  - Self-monitoring and entry of other htn/CV-related parameters
  - Secure electronic messaging with providers
  - Patient-specific recommendations

To few interventions to address how the components worked together as a system of care.

LIMITATIONS

- Too few studies
- Variation in interventions
- Volunteer bias

FUTURE RESEARCH

- 1st phase of research project
- 2nd phase
  - Using the data systematic overview: development of multifaceted patient self-management intervention delivered via a secure patient-controlled personal electronic health record (MyOSCAR)
  - Pilot RCT
    - change in hypertension knowledge
    - patient self-efficacy
    - patient engagement in self-management activities
    - feasibility and acceptability of the intervention to patients and providers

Background

- Strategies for prevention and management of chronic diseases are a priority in primary care
- Time constraints during clinical encounters interfere with:
  - Ability of patients to ask all questions
  - Ability of physicians to provide adequate education
  - Ability to achieve consensus on priorities for management
- Web-based systems can deliver health information and monitor outcomes for lifestyle issues

MyOSCAR: patient controlled personal health record

- **MyOSCAR** has potential to support self-management of chronic disease by allowing patients to control what information is added or modified and to decide who can view or change their record.

MyOSCAR

- Allow patients to **edit/add** and enable **sharing** health information
- **Communication** with healthcare providers through secure messaging system
- **Review/annotate** past and current prescriptions

MyOSCAR

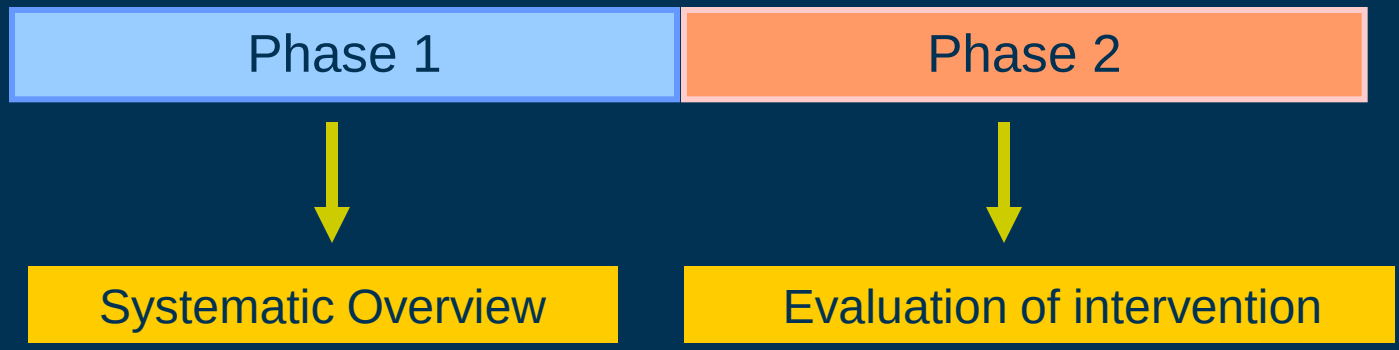
- Exploring ways to integrate the use of MyOSCAR into practice

- The MyBP study:
  - Example of developing new components for MyOSCAR, implementing it, and then evaluating how well it performs.

Research Goal

- To determine the potential value and feasibility of an evidence-based patient self-management strategy for hypertension in primary care

‘MyBP’ Hypertension Self-Management Program



Phase 2: Evaluation of an intervention

Research Questions

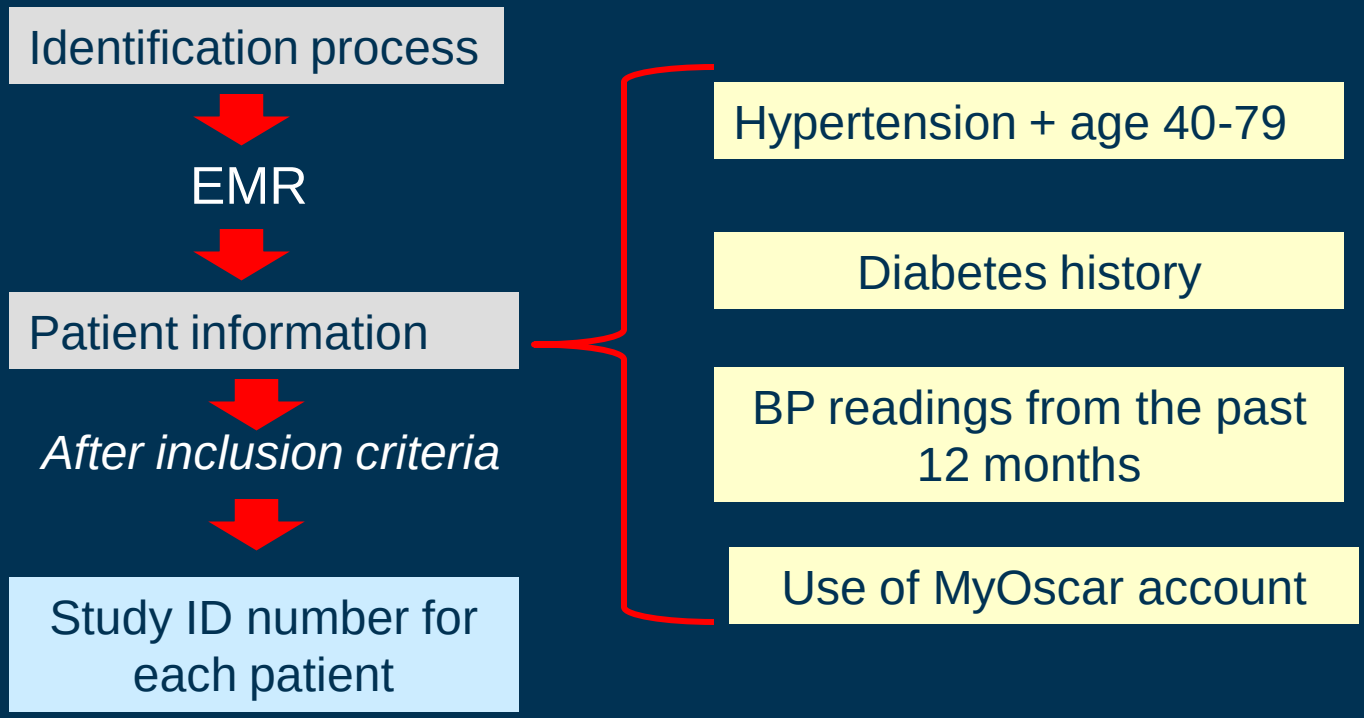
1) What is the uptake, feasibility and ease of use of the e-health self-management strategy (MyBP Program)?

2) What is the potential impact of the intervention on processes of care and patient outcomes?

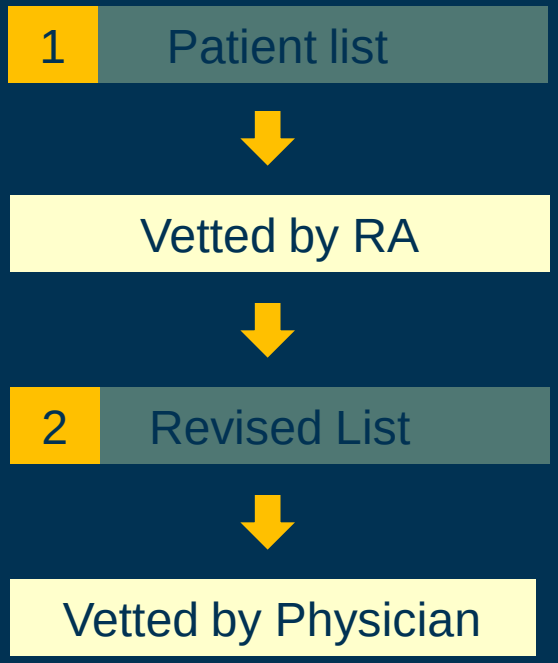
Study Design & Methodology

Design	Pilot randomized controlled trial
Study Length	3 months
Recruitment site	McMaster Primary Health Centre
Inclusion criteria	▪ Between 40 to 79 years of age ▪ Diagnosis of hypertension ▪ Elevated office BP reading in past 12 months (SBP ≥140 mmHg [or ≥130 mmHg if diagnosed with diabetes]) ▪ Regular access to email / internet
Exclusion criteria	▪ Patients with MyOSCAR account

Identification of eligible patients in Oscar EMR



Patient eligibility: Physician vetting



1. Language barrier
2. Terminal illness or other medical condition that would limit participation
3. Patient is expected to be out of the country for at least 3 of the next 6 months
4. Patient on a waiting list for placement to a long term care or assisted living facility

Patient recruitment

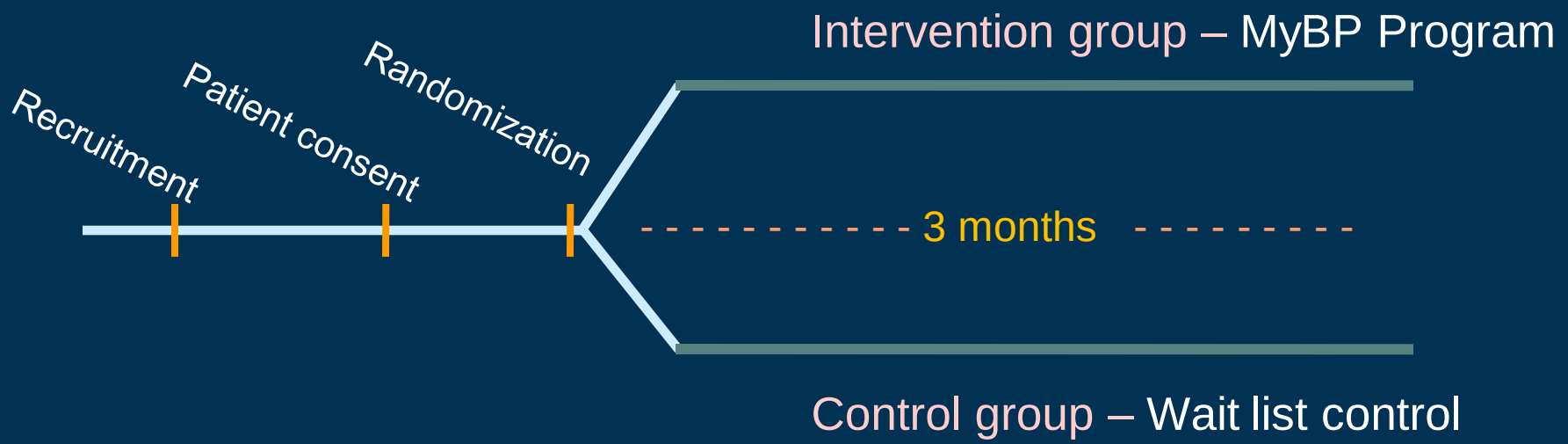
Invitation letter sent with follow-up telephone call for initial verbal consent (followed up with written consent)

Requirements for patients to participate:

- Monitoring of BP
  - Own BP home monitor
  - Borrow BP monitor
  - Buy BP monitor
  - Visit the clinic for self-assessment using the BpTRU
  - Monitor BP with a consistent device at the pharmacy

Regular access to email

Recruitment & Randomization



Baseline visit

Baseline visit

- Provide study information
- Obtain informed, written consent
- BP (BpTRU)
- Weight, height, waist circumference
- Provided with Patient Information Form*
- Calibration of BP monitors (**INT**)
- Surveys

*Form listing BP reading, anthropometric measures, use of antihypertensive medication and most recent lipid profile from the past 12 months

Education session

Education Session

1) Provide information about MyBP Program
2) Demonstration of MyOSCAR
3) Participants practice using MyOSCAR

Follow-up visit

Follow-up visit

-BP (Bp TRU)

- Weight, height, waist circumference

- Provided with Patient information Form*

- Obtain Exercise diary (**INT**; if applicable)

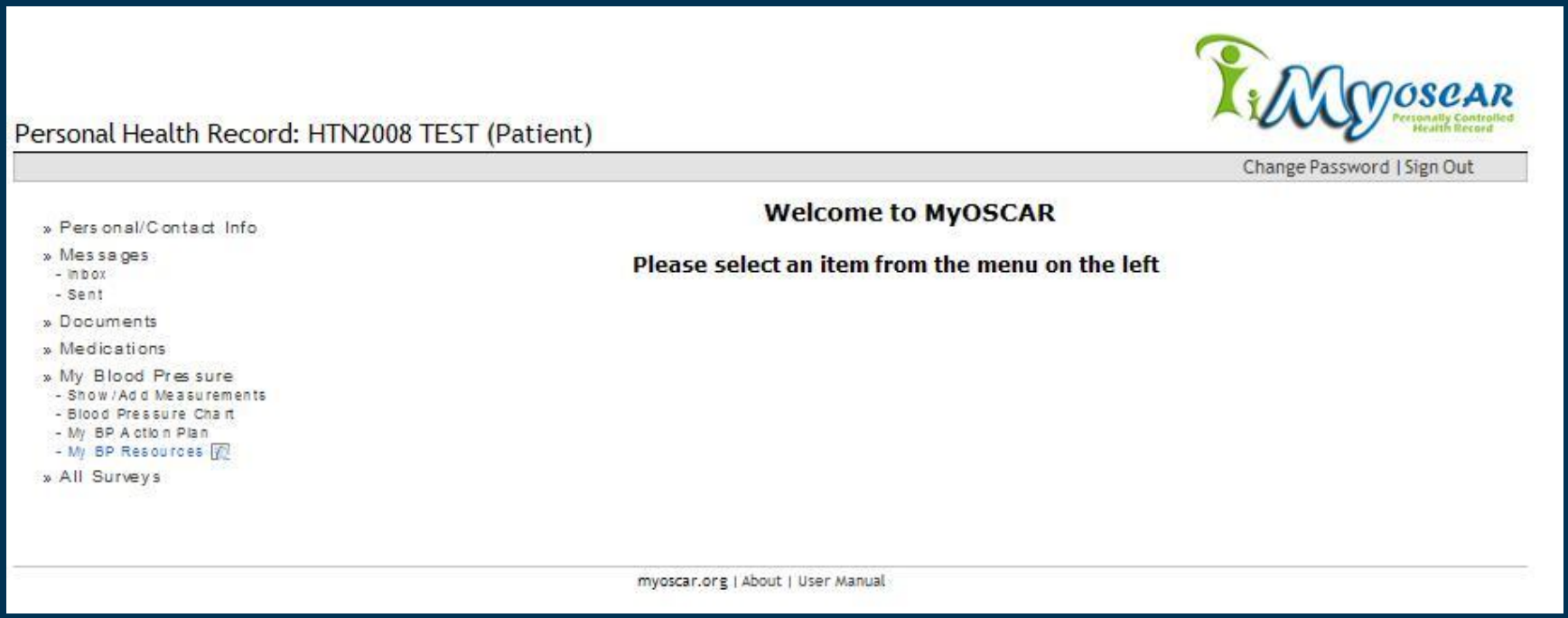
- Surveys

*Form listing BP reading, anthropometric measures, use of antihypertensive medication and most recent lipid profile performed since baseline

MyBP Program Intervention

- Enter BP into **MyOSCAR/myBP** and ability to track their BP over time using the graphing tool
- Received weekly feedback on BP readings entered into **MyOSCAR** from clinical assistant
- Access to allied healthcare providers using secure messaging in **MyOSCAR** (pharmacist, dietitian, and nurse practitioner)
- Completed survey to identify personal cardiovascular risk factors
- Ability to create own personalized BP action plan to implement lifestyle changes to target these risk factors
- Access to information about hypertension (mybloodpressure.ca)

MyOSCAR: Home



MyBP Program: Entering BP readings

At least once a week

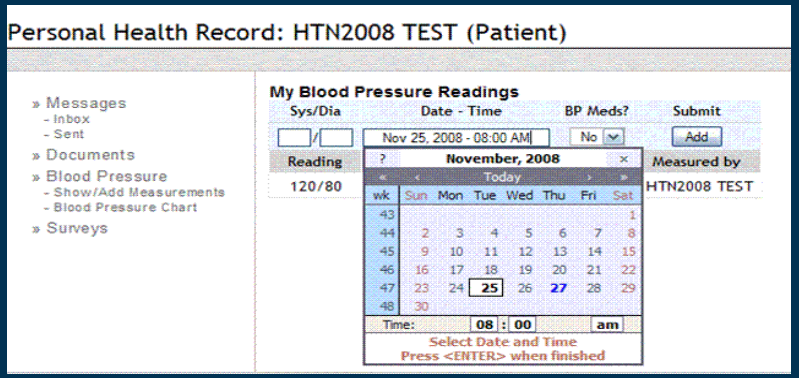
Take BP

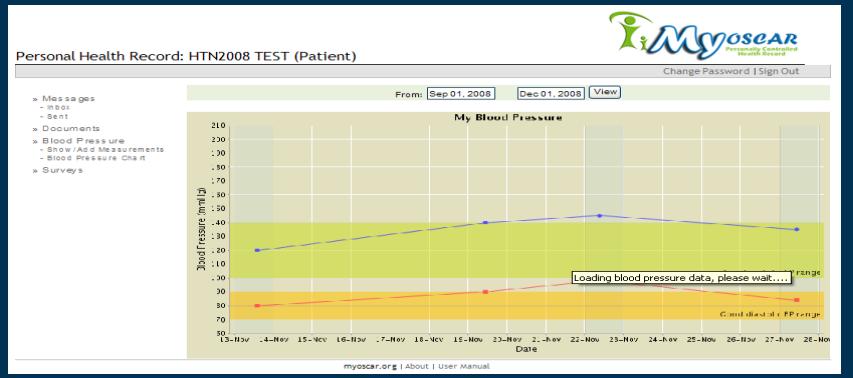
- Home
- Pharmacy
- Healthcare centre

My account

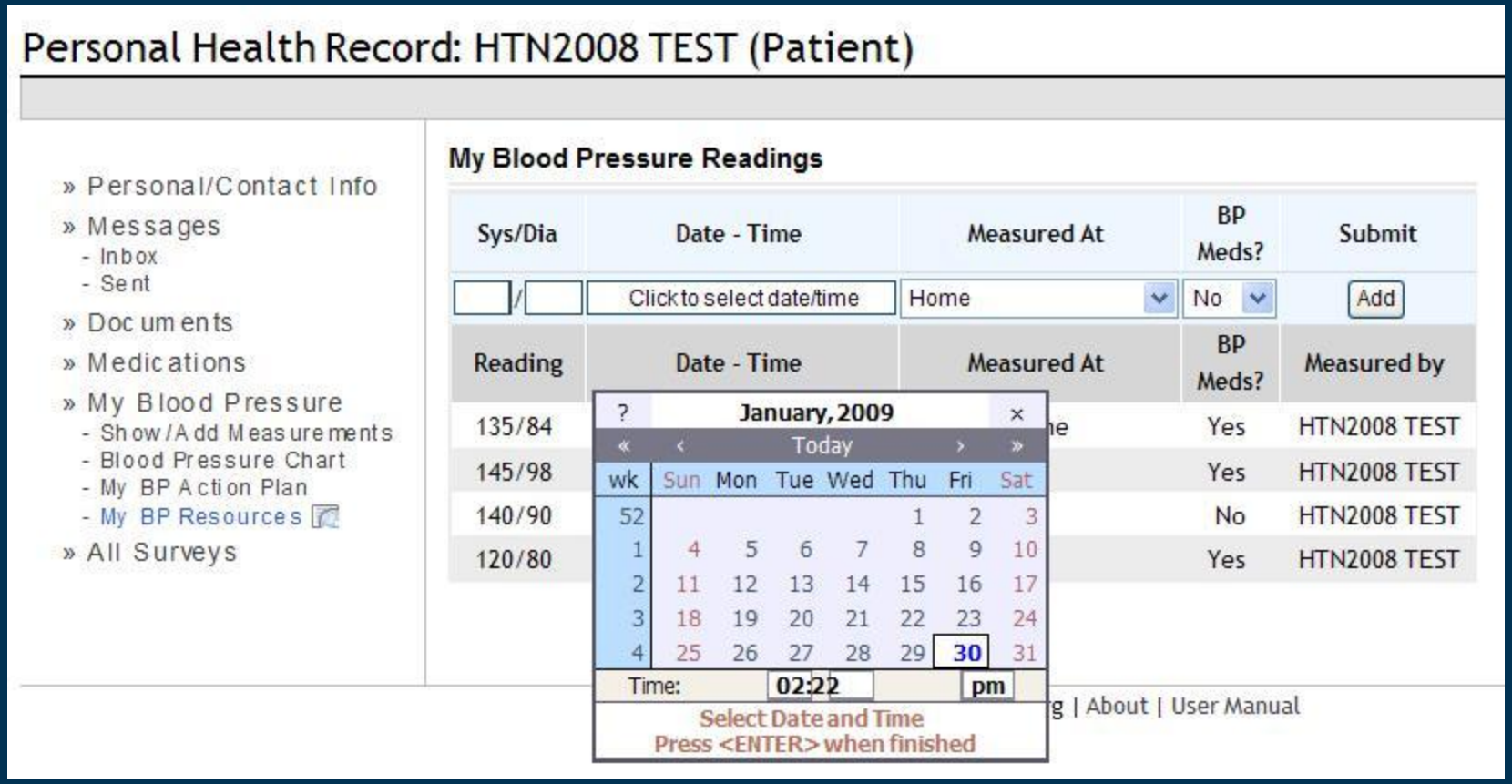
Add BP information

BP graphing features

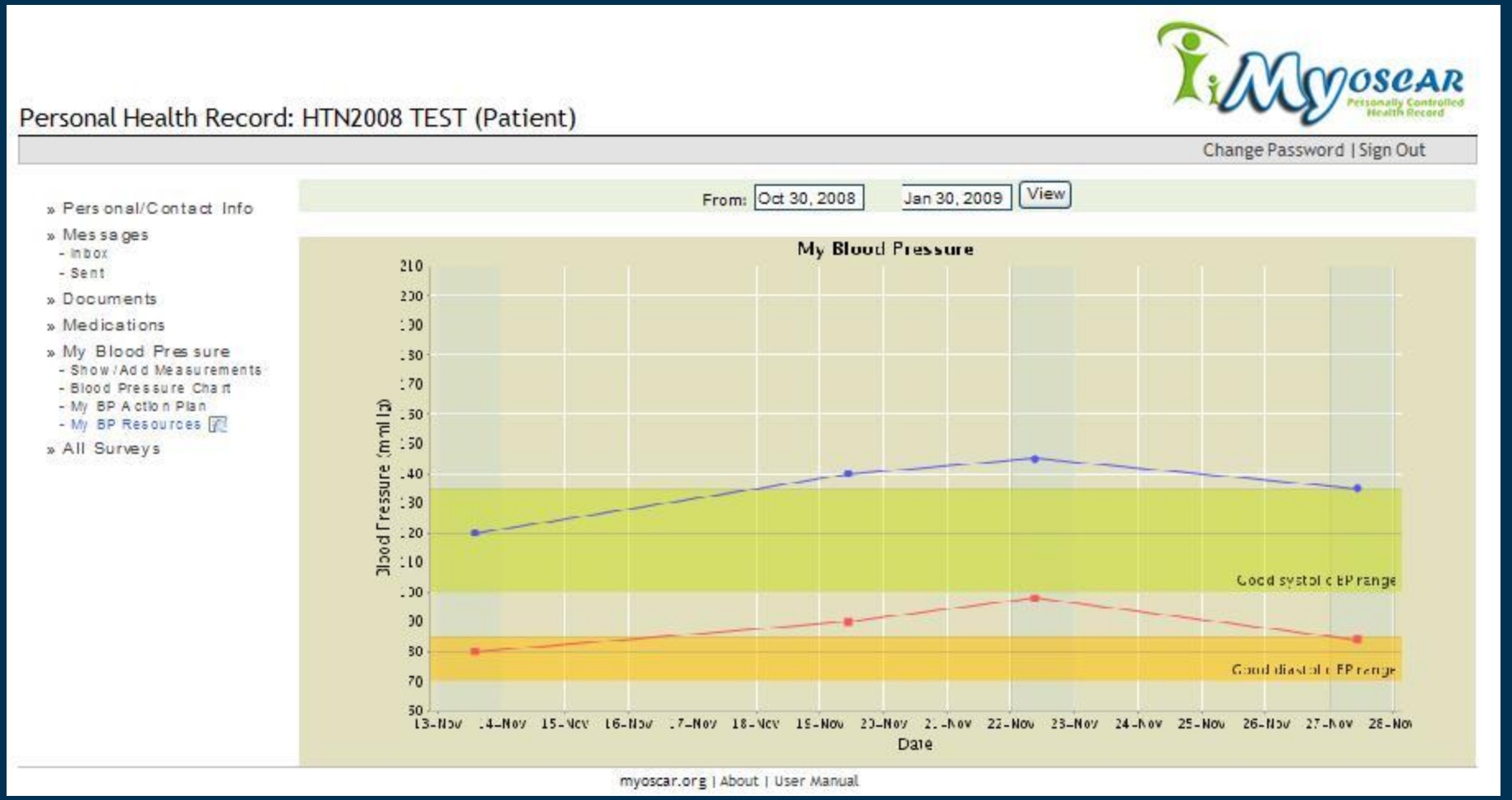




MyOSCAR: Adding BP Readings



MyOSCAR: BP Graphing



MyBP Program: Messaging

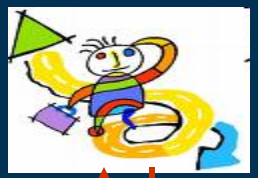
Web Program

Messages

Send New Message

Message inbox

Sent messages



Clinical Assistant

Nurse Practitioner

Pharmacist

Dietician

MyOSCAR: Messaging

MyBP Program: Action Plan

1

survey

2

3

HEART & STROKE FOUNDATION
Finding answers. For life.

Survey completed

4

Clinical Assistant

5

Risk profile

Action Plan Survey

My Action Plan

CV Risk Profile

Heart&Stroke My Risk Assessment Report

My Risk Assessment Comprehensive Report

Welcome to your full Heart&Stroke Risk Assessment Report. This report will give you more information about your personal health risks, based on your answers to our questions. It also provides you with tips to help you improve your health.

Risk Factors You Cannot Change

Some risk factors are things you cannot change or control, such as your age, family history or ethnic background. You can still help to improve your health and reduce your chances of developing chronic diseases such as heart disease and stroke by making healthy lifestyle changes.

Age:
Before menopause, most women have a lower risk of heart disease and stroke than men. But your risk will be higher if you have lifestyle risk factors or have been diagnosed with diabetes, high blood pressure, high cholesterol, kidney disease or a previous heart attack or stroke. Your risk will also increase as you age and enter menopause.

Family History:
You have reported a family history of:

- diabetes or high blood sugar
- high blood pressure
- high cholesterol or unhealthy fats (cholesterol or triglycerides) in the blood
- A family history of heart disease early in life

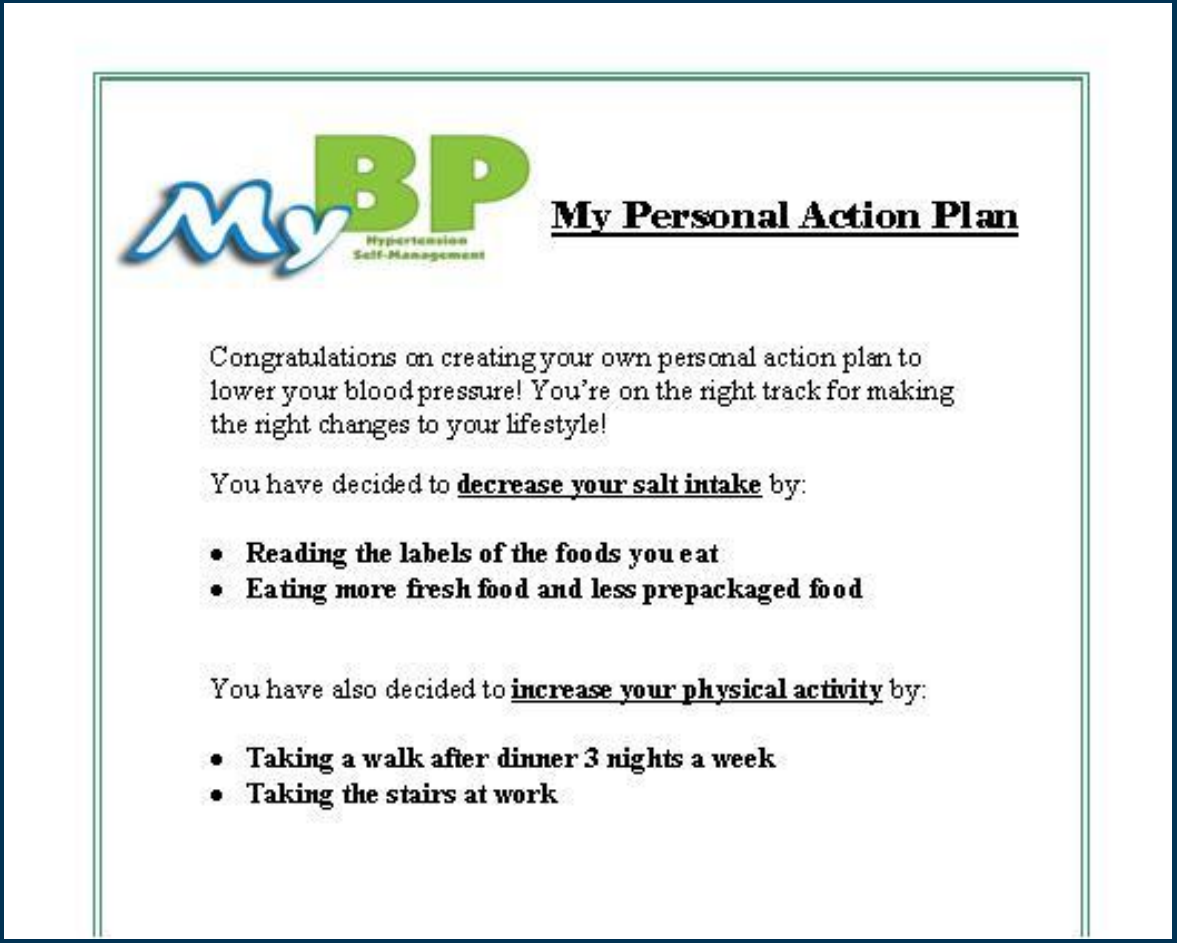
As some diseases are more common in some families, it may mean your own risk is higher than average. The higher risk may be caused by genes you've inherited. Or it may be because people in the same family tend to be alike in the choices they make about diet and healthy living . Having a family history means that you should try to make lifestyle changes to reduce your risk.

Gender:
In general, men are at greater risk of dying from heart disease and stroke than women. But no-one is safe from heart disease and stroke. For women, the risk rises after menopause.

Risk Factors You Can Change or Control

Some risk factors reflect the choices we make in our daily life, such as what we eat or drink and how active we are. Making healthy lifestyle changes in the following areas could help to improve your health, make you feel more energetic, relieve stress and reduce your risk of heart disease, stroke and many other chronic diseases. For this report, we put your risk factors into groups, based on when you said you would be ready to start making healthy changes.

Action Plan Summary



My Personal Action Plan

Congratulations on creating your own personal action plan to lower your blood pressure! You're on the right track for making the right changes to your lifestyle!

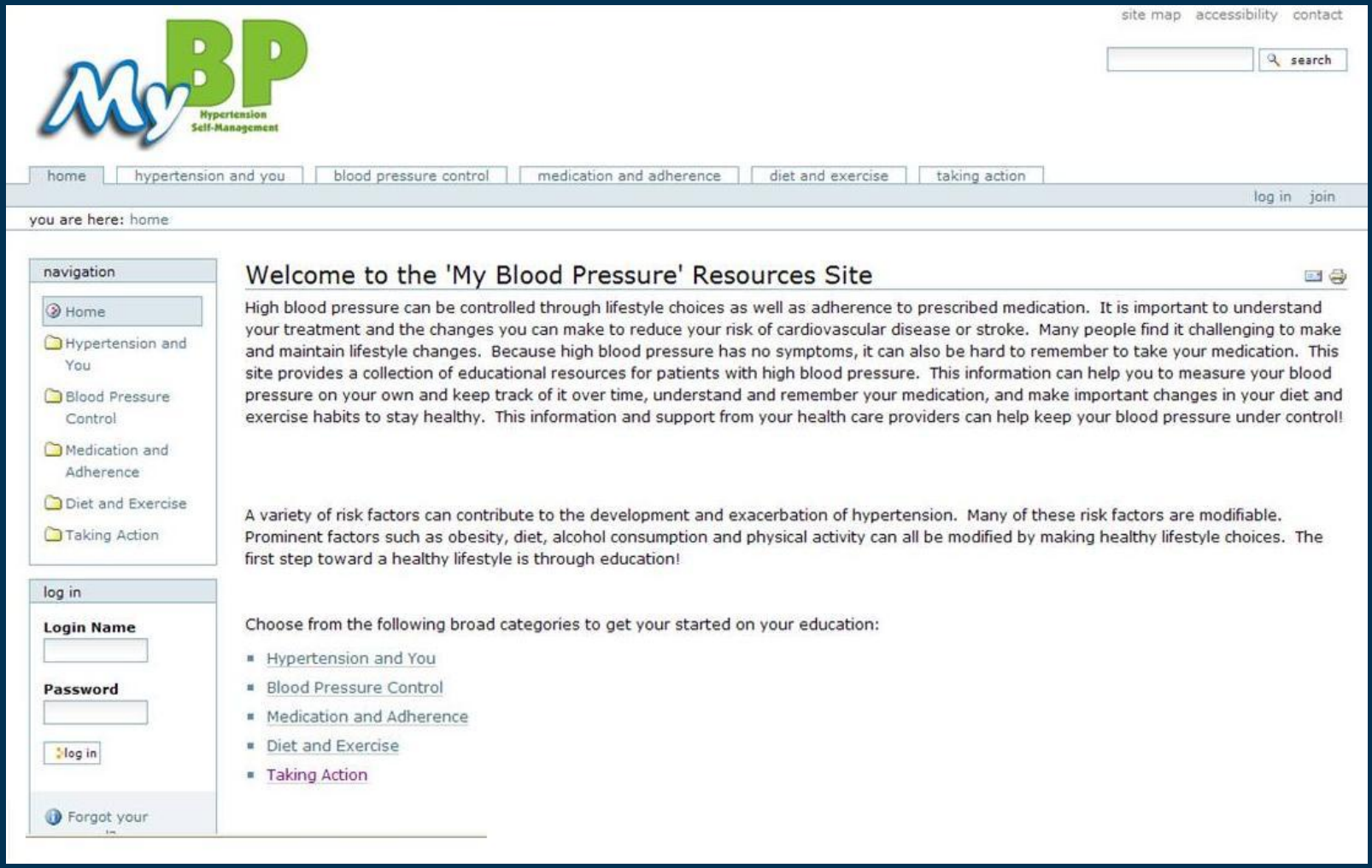
You have decided to **decrease your salt intake** by:

- **Reading the labels of the foods you eat**
- **Eating more fresh food and less prepackaged food**

You have also decided to **increase your physical activity** by:

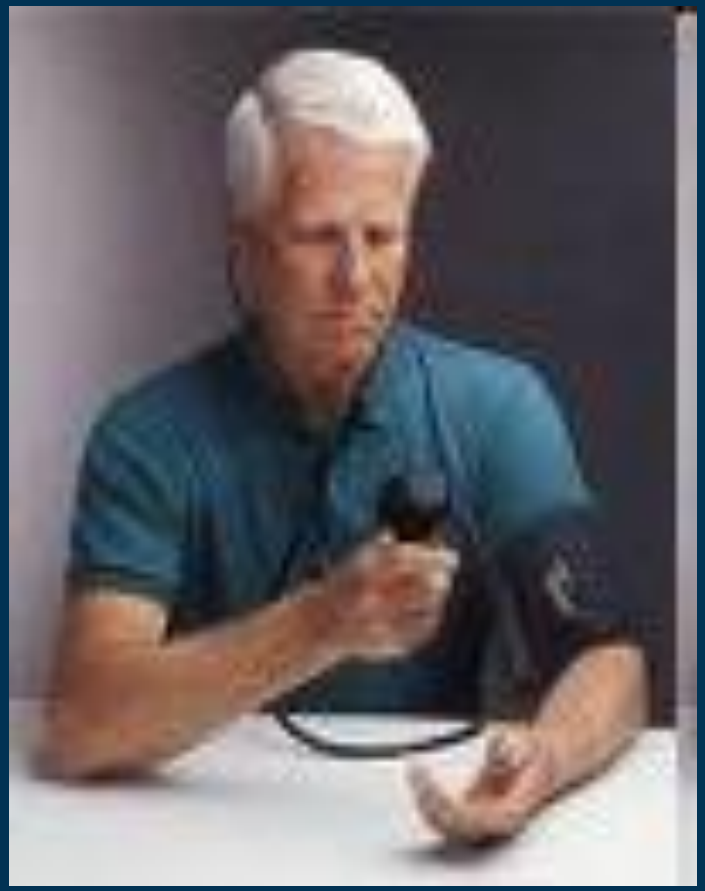
- **Taking a walk after dinner 3 nights a week**
- **Taking the stairs at work**

MyBP: Resources



MyBP Program

“I've been pleased with my progress and choices over the past week. I've been able to log most or all of my food intake on most days. I have mostly been meeting my objectives for lots of fruits & vegetables, low-fat foods, and water. My weight is finally dropping a couple of pounds. I've been walking 6,500 - 10,000 steps a day over the past week. And my blood pressure is coming down a few points. Now I'm looking forward to seeing it in the target range. Thanks for this program which is giving me a way to measure my progress, especially in such a visible, tangible way as the BP chart.”



Data Collection

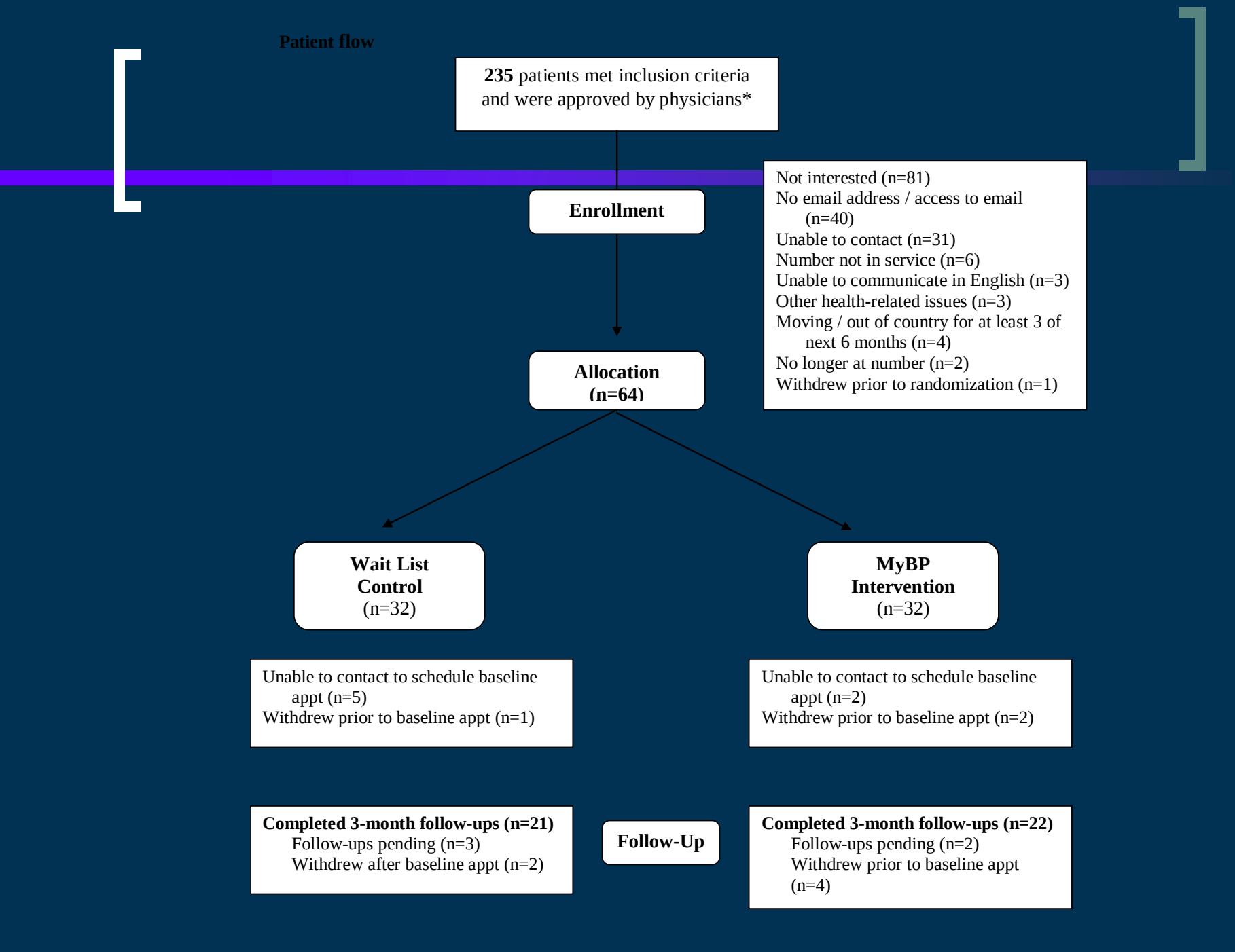
- BP measurement (BP Tru)
- Patient Information Form: anthropometric measurements, lipid profile, use of antihypertensive medications, diagnosis of diabetes.
- Extent of Program resource use (BP entries, # secure messages exchanged with providers)
- The content of messages exchanged with study healthcare providers and study team
- A chart audit to capture number of visits to providers, number of out-of-office BP readings, and changes in management
- Survey administration to assess patient satisfaction; changes in patient knowledge; self-efficacy; medication adherence; and engagement in self-management activities.

Data Analysis

- Quantitative data: descriptive statistics (means, SDs, proportions) for baseline demographic data, extent of program resource use, blood pressure results, patient satisfaction etc...

- Qualitative data: review of content of messages for key themes

Results


Patient flow
235 patients met inclusion criteria and were approved by physicians*
Enrollment
Not interested (n=81)
No email address / access to email (n=40)
Unable to contact (n=31)
Number not in service (n=6)
Unable to communicate in English (n=3)
Other health-related issues (n=3)
Moving / out of country for at least 3 of next 6 months (n=4)
No longer at number (n=2)
Withdrew prior to randomization (n=1)
Allocation (n=64)
Wait List Control (n=32)
MyBP Intervention (n=32)
Unable to contact to schedule baseline appt (n=5)
Withdrew prior to baseline appt (n=1)
Unable to contact to schedule baseline appt (n=2)
Withdrew prior to baseline appt (n=2)
Completed 3-month follow-ups (n=21)
Follow-ups pending (n=3)
Withdrew after baseline appt (n=2)
Follow-Up
Completed 3-month follow-ups (n=22)
Follow-ups pending (n=2)
Withdrew prior to baseline appt (n=4)

Results

Patient characteristics at baseline

Characteristic	Intervention group (n=28)	Control group (n=26)
Age (years, mean [SD])	64.1 (8.3)	63.6 (9.2)
% Female	60.7	46.2
Diagnosis of diabetes (n[%])	10 (35.7)	14 (53.8)
Waist circumference (cm; mean [SD])	102.8 (16.5)	107.5 (14.1)
Weight (kg; mean [SD])	87.2 (19.9)	91.2 (18.9)
Taking antihypertensive medications (n [%])	24 (85.7)	25 (96.2)

Results

Blood Pressure

	Intervention group		Control group	
	Pre **(n=28)**	Post **(n=21)**	Pre **(n=26)**	Post **(n=20)**
Systolic BP (mmHg; mean [SD])	129.4 (13.0)	128.1 (15.8)	129.3 (17.0)	127.1 (11.7)
Diastolic BP (mmHg, mean [SD])	75.4 (8.5)	77.1 (8.6)	79.3 (10.9)	75.6 (7.9)
Elevated systolic BP (n [%]	8 (28.6)	6 (28.6)	7 (28.0)	7 (35.0)

Results

Use of MyBP Program components

- 92.9% of patients (n=26) in the intervention group used the MyBP Program
- 80% of intervention patients created a Personal Action Plan

Cardiovascular Risk Factors Targeted by Personal Action Plans	n (%)
Physical Inactivity	15 (71)
Diet	10 (47.6)
BMI	6 (28.5)
Stress reduction	3 (14.2)
Salt intake	1 (4.7)
Alcohol intake	1 (4.7)
Smoking	0

Preliminary Results

Messaging with allied HCP

- 35.7% of intervention patients have sent messages to the study allied HCP (n=10)
- 19 patient messages were sent to allied HCP by MyBP Project Support

Messages sent to allied healthcare providers	n (%)
Nurse Practitioner	12 (57.1)
Dietitian	6 (28.6)
Pharmacist	3 (14.3)

Results

Usability of MyBP Program

- 21 intervention patients completed the MyBP Feedback Survey ~1 month after their education session (87.5%)

Results

- 89.6% of participants have completed their 3-month follow-up visit (43 of 48)
- All intervention group patients who have completed their follow-up visit wish to continue to monitor and enter their BP readings into their MyOSCAR account (n=22)
- 21 of 22 intervention group patients wish to continue to receive feedback on their BP readings

Discussion:

- Successful in demonstrating feasibility but still not determined to be effective (this pilot study was not designed to test effectiveness).
- 25% of those screened eventually enrolled in the study; despite searching for uncontrolled patients based on chart review many were controlled at baseline visit with validated BP device.
- Development of numerous study processes, technical documents, patient training session and manual
- Patient controlled health record was foundation of intervention but it also included human components
  - Clinical assistant
  - Health care providers

Future developing: Notes from Post study sustainability meeting

- If already have a relationship with the patient then the patient is much more likely to email the health care provider so need to take steps to foster this relationship in person then use of email to follow.
- Helpful to have clear criteria for patients of how the messaging is to be used, when to use it and what it should be used for ; triage of messages makes things more efficient
- myOSCAR has an audit trail which is helpful for medical-legal reasons
- consider giving group rights for messages such as the group of pharmacists vs just one pharmacists which will help with cross coverage
- adding in a scheduling program
- Healthcare professionals should be able to see the clinical values entered by patients without having access rights to patient's myOSCAR record – eg, integrate with their EMR
- incorporate the Vascular Tracker (since David did already develop a version for COMPETE) adapting the tracker for patients
- put in program to count calories perhaps from the Canada Food Guide
- care integration with home monitoring devices
- need to consider the concept of 'myfamilies' versus only having an OSCAR user as a stand alone per patient.
- Consider moving from monitoring to tutoring paradigm more active paradigm for behaviour change.
- Allow data entry from smart phones (e.g. iphone has a blood glucose app)
- Identify what motivates physicians to participate (e.g. having a triage person)
- Use of texting? Can the application be adapted? How to authenticate a person through SMS?

Automating myBP messages (Norm Archer (PI)

- All messages sent by patients were categorized by topic and criticality
- Computer programmer reviewing messages and determining feasibility of automating responses

Questions? Comments?