May Measurement Month

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/01/2019		☐ Protocol		
Registration date 13/02/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 20/09/2021	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Background and study aims

In 2017, the International Society of Hypertension (ISH) conducted a global blood pressure screening survey across about 100 countries, collecting data from over 1.2 million participants. Following the success of the 2017 campaign, in 2018, ISH proposes to conduct a second global blood pressure (BP) survey of volunteer adults (aged 18 and over) who ideally have not had their BPs measured for at least a year before BP screening.

Who can participate?
Volunteers aged 18 and over

What does the study involve?

Basic demographic and clinical information as well as BP measurements are collected by health profession volunteers throughout May 2018. Sitting blood pressure is measured three times according to standardised specified methods. Participants whose BP readings are consistent with the current definition of hypertension are provided with written dietary and lifestyle advice. They are also provided with a referral to receive medications and/or follow up support, according to local facilities.

What are the possible benefits and risks of participating?

Participants will benefit from individual and immediate feedback on their blood pressure status and, where blood pressure is above targets, they are given lifestyle advice and a card with their blood pressure readings and the suggestion to confirm the readings with their GPs at the earliest possible opportunity. There are no serious risks to the participants. Blood pressure cuff inflation may cause minor discomfort. People asked to see their GP at some point might develop concerns or anxiety about this – the MMM team will provide written explanations of the lack of risk involved in being asked to see the GP due to a potentially raised blood pressure.

Where is the study run from? Imperial College School of Medicine (UK)

When is the study starting and how long is it expected to run for? September 2017 to April 2019

Who is funding the study?

- 1. International Society of Hypertension (UK)
- 2. Centers for Disease Control and Prevention (USA)
- 3. Servier (France)

Who is the main contact?

- 1. Prof. Neil Poulter
- 2. Prof. Francesco Cappuccio
- 3. Lisa Woodward

Study website

http://maymeasure.com/

Contact information

Type(s)

Scientific

Contact name

Prof Neil Poulter

Contact details

Imperial College School of Medicine London United Kingdom W12

Type(s)

Scientific

Contact name

Prof Francesco Cappuccio

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Contact details

University of Warwick Warwick Medical School Coventry Zimbabwe CV4 7AL

Type(s)

Public

Contact name

Ms Lisa Woodward

Contact details

ISH c/o Imperial College School of Medicine London United Kingdom W12

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

International 2.1

Study information

Scientific Title

UK contribution to May Measurement Month, a global strategy to measure blood pressure in 25M people across the world

Acronym

MMM18

Study objectives

To screen at least 1 million people aged ≥ 18 years who ideally have not had their BPs measured for at least a year prior to the current BP screening.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Health Research Authority, North East – York Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne NE2 4NQ, Local contact: Ms Kerry Dunbar, REC Manager, Tel: +44 (0)207 104 8082, Email: nrescommittee.northeast-york@nhs.net, 08/02/2018, REC ref: 17/NE/0087, IRAS project ID: 225418

Study design

Cross-sectional survey in a convenience population sample

Primary study design

Observational

Secondary study design

Epidemiological study

Study setting(s)

Community

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

High blood pressure (hypertension)

Interventions

The survey will be conducted in approximately 100 countries each incorporating a variable number of screening sites. Basic demographic and clinical information as well as BP measurements will be collected by health profession volunteers throughout May 2018. Sitting blood pressure will be measured in triplicate according to standardised specified methods. The data will be anonymised, coded and transferred electronically (through a purpose-designed application or using an Excel spreadsheet) to a central AWS DynamoDB database. Screenees whose BP readings are consistent with the current definition of hypertension will be provided with written dietary and lifestyle advice. Participants will also be provided with a referral to receive medications and/or follow up support, according to local facilities.

Intervention Type

Behavioural

Primary outcome measure

Systolic and diastolic blood pressures and pulse rate measured up to three times in the sitting position after 5 min rest using automated blood pressure monitors or, if unavailable, ordinary sphygmomanometer. Measurements taken once at baseline.

Secondary outcome measures

Measure of body mass index (in kg/m2) taken as weight in kg or lb (converted in kg) and height in cm or ft and inch (and converted in cm). Measures will be either self-reported or measured with a stadiometer and electronic weighing scales. Measurements taken once at baseline.

Overall study start date

01/09/2017

Completion date

30/04/2019

Eligibility

Key inclusion criteria

- 1. Age ≥ 18 years
- 2. Consent for participation given according to local requirements

Participant type(s)

Αll

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1 million

Key exclusion criteria

Unable to provide informed consent

Date of first enrolment

01/05/2018

Date of final enrolment

31/05/2018

Locations

Countries of recruitment

England

Ireland

United Kingdom

Study participating centre Imperial College School of Medicine

Clinical Trial Unit White City Campus London United Kingdom W12 0BZ

Sponsor information

Organisation

International Society of Hypertension

Sponsor details

ISH Secretariat c/o The Conference Collective Ltd. 8 Waldegrave Road Teddington United Kingdom TW11 8HT

Sponsor type

Charity

Website

http://ish-world.com/contact.htm

Funder(s)

Funder type

Charity

Funder Name

International Society of Hypertension

Alternative Name(s)

ISH

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Centers for Disease Control and Prevention

Alternative Name(s)

United States Centers for Disease Control and Prevention, Centros para el Control y la Prevención de Enfermedades, Centers for Disease Control, U.S. Centers for Disease Control and Prevention, CDC, U.S. CDC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Funder Name

Servier

Alternative Name(s)

Servier Laboratories, Laboratoires Servier

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

France

Results and Publications

Publication and dissemination plan

- 1. To present at national and international meetings
- 2. To publish in international journals
- 3. To hold public engagement meetings
- 4. To use dissemination by media

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The data will be stored at Imperial College CTU in anonymised form. The MMM team (under the overall responsibility of Prof. Neil Poulter and Senior Statistician Thomas Beaney) will handle analyses centrally. Written informed consent was provided by each participant. For further information visit http://maymeasure.com/.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details Global results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2019	20/09/2021	Yes	No
HRA research summary			28/06/2023	No	No