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#### Citation

Masami Ito, Rie Toyomoto, Sanae Kishimoto, Masatsugu Sakata, Yukiko Honda, Hissei Imai, Aran Tajika, Toshiaki A. Furukawa. Nurse-led interventions for blood pressure control: A systematic review and meta-analysis. PROSPERO 2021 CRD42021246085 Available from:

https://www.crd.york.ac.uk/prospero/display record.php?ID=CRD42021246085

# Review question

- P: Adults aged 18 years and over with hypertension.
- I: Care as usual in the primary care and nurse-led blood pressure control interventions in the community.
- C: Care as usual in the primary care
- O1: The achievement of blood pressure control goals at one year (range: 0.5 to 3 years)
- O2: Serious adverse events
- O3: The average change of systolic blood pressure (SBP) / diastolic blood pressure (DBP) from baseline.
- O4: The rate of using hypertension medicine
- O5: The rate of adherence
- O6: The incident rate of hypertensive complications including cardiovascular events and strokes
- O7: The mortality rate
- (O1-O2: primary outcomes, O3-O7: secondary outcomes)

# Searches

CiNii Articles.

We will search the following electronic databases:

CENTRAL(Cochrane Central Register of Controlled Trials);

PubMed;
CINAHL;
???Web;
?????Web;

We will not use any language restrictions.

# Types of study to be included

We will include all published and unpublished randomized controlled trials (RCTs). We include only the first



phase of cross-over studies. We will also include cluster-randomized trials if the intracluster (or intraclass) correlation coefficient (ICC) can be estimated.

# Condition or domain being studied

Hypertension. Adults aged 18 years or over.

# Participants/population

Inclusion: Adults aged 18 years or over, with hypertension.

Exclusion: Pregnant women.

# Intervention(s), exposure(s)

Experimental intervention: Nurse-led blood pressure control interventions in the community, in addition to care as usual in the primary care.

Nurses will include any professionals with relevant state qualifications, such as nurses, assistant nurses (????), and public health nurses (???) in the case of Japan.

# Comparator(s)/control

Control intervention: Care as usual in the primary care.

#### Context

The interventions can take place in clinics for primary care, pharmacies, health centers, nursing homes, and facilities for the elderly people.

# Main outcome(s)

?The achievement rate of the goals for blood pressure control, according to the original authors' definition.

?Serious adverse events.

# Measures of effect

We will use the risk ratio (RR) and report 95% confidence intervals (CI) about dichotomous outcome. We will also use the mean difference (MD) and report 95% confidence intervals (CI).

# Additional outcome(s)

?The average score change of systolic blood pressure (SBP) / diastolic blood pressure (DBP) from baseline.

?The rate of using hypertension medicine

?The rate of adherence

?The incident rate of hypertensive complications including cardiovascular events and strokes

?The morality rate

#### Measures of effect

We will use the risk ratio (RR) and report 95% confidence intervals (CI) about dichotomous outcome. We will also use the mean difference (MD) and report 95% confidence intervals (CI).

# Data extraction (selection and coding)

Selection of studies

The pairs of review authors will independently identify the titles and abstracts of all potential studies retrieved from the searches. We will retrieve the full article and independently decide which studies have met all eligibility criteria. We then will document the reasons for exclusion before deciding on exclusion. The pair of authors will discuss any disagreement about the inclusion. We will consult a third review author of the team if we cannot resolve their different opinions. Also, we will attempt to contact the authors of the study for clarification when it is not possible to resolve the disagreement by discussion.



Data extraction and management

The review authors will construct a data extraction form using excel spreadsheets and will independently extract data from all included studies.

The following characteristics will be extracted from included studies:

?Study name

?Year of publication

?Type of setting

?Country

?Diagnostic criteria used

?The group-average demographics (number of participants allocated, age, sex, baseline blood pressure)

?Duration and details of the intervention

?Outcome measures, timing of measures, the type of blood pressure monitors, and the goal of hypertension

?Results

The review authors will independently fill out the forms and check them. They also will discuss any disagreement and note the decisions. The third review author will resolve their disagreements. They will attempt to contact the authors to get missing information if necessary. They will document these final decisions. A review author will transfer data into the Review Manager 5 (Review Manager 5.4).

## Risk of bias (quality) assessment

The pairs of review authors will independently assess the risk of bias of the included studies using the version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB2) in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2020).

We will use the following items to assess the risk of bias in the included studies.

?Risk of bias arising from the randomization process

?Risk of bias due to deviations from the intended interventions

?Risk of bias due to missing outcome data

?Risk of bias in measurement of the outcome

?Risk of bias in selection of the reported result

We will grade each risk of bias as High, Low, or Some concerns for every domain. We will finally assess the risk of bias with the third review author when we disagree.

#### Strategy for data synthesis

We will analyze data using Review Manager 5.

We will use the risk ratio (RR) and report 95% confidence intervals (CI) about dichotomous outcome. We will also use the mean difference (MD) and report 95% confidence intervals (CI). We will use a random-effects model for all analyses, because we ancitipate clinical heterogeneity about various interventions by nurses.

Analysis of subgroups or subsets



We will perform the following subgroup analyses:

?The intervention for blood pressure control (physicians and nurses/ others including nurses);

?Setting (nurse interventions taking place in primary care clinics/ taking place in the communities including pharmacies, health centers, nursing homes and facilities for the elderly people);

?Regions (North America/ Europe/ Asia /Others);

?Prescription by nurses;

?The goal of blood pressure ("SBP140mmHg/DBP90mmHg"/ more / less).

#### Contact details for further information

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# Organisational affiliation of the review

Department of Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine / School of Public Health

http://ebmh.med.kyoto-u.ac.jp/index.html

# Review team members and their organisational affiliations [2 changes]

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# Type and method of review

Intervention, Meta-analysis, Systematic review

# Anticipated or actual start date

01 April 2021

# Anticipated completion date

15 January 2022

# Funding sources/sponsors

Intramural funding.

# Conflicts of interest

TAF reports grants and personal fees from Mitsubishi-Tanabe, personal fees from MSD, grants and personal fees from Shionogi, outside the submitted work; In addition, TAF has a patent 2020-548587concerning smartphone CBT apps pending, and intellectual properties for Kokoro-app licensed to Mitsubishi-Tanabe.



AT has received lecture fees from Mitsubishi-Tanabe, Dainippon-Sumitomo, Otsuka, Janssen, Takeda, and Meiji-Seika Pharma.

HI reports lecture fees from Mochida Pharmaceutical, personal fees from Mitsubishi-Tanabe pharma, personal fees from Kyowa pharmaceutical, outside the submitted work.

Yes Language English

Country Japan

Stage of review Review Ongoing

Subject index terms status Subject indexing assigned by CRD

Subject index terms
MeSH headings have not been applied to this record

Date of registration in PROSPERO 30 April 2021

Date of first submission 30 March 2021

Stage of review at time of this submission [2 changes]

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

# Revision note

We updated the progress status.

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

# Versions





30 April 2021 30 April 2021 12 October 2021 13 February 2022