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[Intervention Protocol]

Remote digital monitoring for selected chronic diseases in primary health care

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the benefits and harms of remote digital monitoring for adults with selected chronic diseases (hypertension, type 2 diabetes, chronic obstructive pulmonary disease, congestive heart failure, and asthma) in primary healthcare settings.

BACKGROUND

Description of the condition

Chronic disease (CD), also referred by the World Health Organization (WHO) as non-communicable disease, are illness that persist for a long period (Bernell 2016), and are the result of a combination of genetic, physiological, environmental, and behavioural factors (WHO 2022). Each year, 41 million people die from CD-related causes, equivalent to 71% of all deaths globally (WHO 2022). An estimated 80% (32.8 million) of all CD-related deaths are due to cancer, chronic respiratory diseases, and diabetes (Benette 2018). One of three people admitted to hospital have five or more chronic conditions (BMJ 2021). CDs impose a large financial burden, and caused an estimated global output loss of USD 47 trillion between 2011 and 2025 (Ghebreyesus 2018).

The target group in this review are individuals with the following chronic diseases treated in primary health care: hypertension, type 2 diabetes, chronic obstructive pulmonary disease (COPD), heart failure, and asthma.

Remote digital monitoring (RDM) applications enable the transmission of a person's biometric data, and communication between people and their healthcare providers despite geographical distance between the individuals (Bisio 2015).

According to WHO, primary health care (PHC) is the most inclusive, effective, and efficient way to reduce premature mortality from chronic diseases (WHO 2019). Care delivery models in PHC settings typically include follow-up of people with chronic diseases through face-to-face and telephone contacts. However, the increasing burden of CD, due to an aging population and a shortage of healthcare providers (Beard 2016), imposes stress on the entire health care system (Murray 2020; Walker 2019). In an attempt to address these challenges, RDM is being steadily introduced into PHC, especially since the COVID-19 pandemic (Muller 2022).

Description of the intervention

Innovative use of technology needs to be integrated at the system level to meet the public health demands (Dinesen 2016). RDM has other names in the literature, e.g. remote monitoring (Flodgren 2015), remote patient monitoring (Muller 2022), Biometric Monitoring Technologies (Manta 2020), and telemonitoring platform (Bisio 2015). In this review, we will use the term RDM for all these terminologies.

Flodgren and colleagues have described RDM as a subcategory of telemedicine technology, and explained that it “allows the clinician, the patient, or both, to respond and adjust treatment regimens in a more immediate way than would be possible with, for example, routine clinic visits” (Flodgren 2015). The functions of RDM applications can be divided into four segments: (a) people who need to be monitored; (b) sensors, devices, and systems; (c) hubs; and (d) final destination (Bisio 2015).

1. **People who need to be monitored** can use RDM applications to transfer physiological data (e.g. blood pressure, heart rate, electrocardiogram, weight, sleep pattern, motion), and psychological health indicators (such as measures used for happiness, self-esteem, depression, loneliness, etc. (Kitsiou 2015)).
2. **Sensors, devices, and systems** are used to measure different modalities of physical quantities (e.g. blood pressure, weight, temperature, blood glucose level). The physical quantities can be entered manually into the RDM application or transferred to the RDM application by connected devices (e.g. wearable technologies and intelligent sensors (Wootton 2012)).
3. **Hubs** transmit collected data from the person’s RDM application to the final destination by internet or smart devices connected to the internet, such as smartphones, smartwatches, or smart tablets (Bisio 2015).
4. **Final destination** is the healthcare provider, such as a PHC provider. The healthcare provider can monitor health data (Malasinghe 2019; Wootton 2012), communicate (synchronously or asynchronously) with the person via the RDM platform (Watson 2020), and make decisions, as a part of the treatment, by providing clinical feedback, care management, and education (Farias 2020; Kitsiou 2015).

Four technical viewpoints are outlined as critical factors for RDM: (a) connectivity; (b) usability; (c) quality of transmitted data; and (d) data processing.

1. **Connectivity** refers to the interoperability between sensors and the hub, and between the hub and final destination (Bisio 2015).
2. **Usability** stands for the ease of transmitting biometric data by users (Pecchia 2011).
3. **Quality of transmitted data** must be taken into consideration during clinical decision-making (Manta 2020).
4. **Data processing** comprise of cleaning, analysing, and managing raw data before assuring their fitness for decision-making (Abdolkhani 2019).

How the intervention might work

Novel digital solutions in health systems may enable new forms of interventions and activities (Davis 2014).

RDM has the potential to enhance access to care, early detection of adverse events, and may possibly improve a person's adherence to a recommended medical treatment (Chan 2021; Wilner 2021). Gathered RDM data may help to reduce unnecessary hospital admissions by early assessment and management of CD (Thomas E 2021). People with CD report that RDM increases their disease-specific knowledge, triggers earlier clinical assessment and treatment, and improves self-management and shared decision-making (Walker 2019).

RDM used in PHC offers the potential to enhance health outcomes, resulting in a reduced burden on all healthcare systems, and increased patient satisfaction (Malasinghe 2019; Thomas NA 2021).

Reported challenges for implementing RDM are workforce training, establishing an extensive care team, and financing (Dinesen 2016). Other barriers can also be related to the national telehealth infrastructure, lack of guidance (e.g. implementation guidelines and evidence-based research (Houlding 2021; Oluoch 2016), and regulatory barriers (e.g. liability and legal issues (Gajarawala 2021)). Factors that may affect access to RDM are: place of residence, age, gender, ethnicity, occupation, health literacy, digital literacy, access to RDM, type of disabilities, and healthcare providers' willingness to offer or promote RDM (Dinesen 2016; Houlding 2021). We will assess

factors of equity according to *Equity considerations in EPOC reviews* (Welch 2022).

Why it is important to do this review

As mentioned earlier, the WHO considers primary health care to be the most inclusive, effective, and efficient way to reduce premature mortality from chronic diseases (WHO 2019). While PHC care delivery models typically include following people with chronic disease through face-to-face and telephone contacts, the aging population and shortage of healthcare providers (Beard 2016), are stressing the entire health care system (Murray 2020). RDM has been steadily introduced into PHC to address these challenges, especially since the COVID-19 pandemic (Muller 2022).

RDM for people with CDs has the potential to change the way PHC is organised (Iqbal 2021; Muller 2022; Peyroteo 2021), by increasing the focus on early diagnostics and preventive care (Farias 2020; Kitsiou 2015). RDM may also lead to better medical outcomes (Milan 2020), reduced healthcare costs (Oluoch 2016), reduced hospitalisation (Milan 2020; Vestbo 2012), and improved disease-specific knowledge, resulting in better self-management by the person with CDs (Hanley 2015).

Due to the rapid development of RDM, numerous clinical studies are being carried out globally. Most published studies have focused on RDM in specialist care settings. However, little is known about the benefits and harms of RDM in the PHC setting, especially in low- and middle-income countries (LMICs), groups of minorities, and people of low socioeconomic status.

This Cochrane Review will contribute important evidence for healthcare personnel, policy- and decision-makers, and people with CDs, by filling the existing knowledge gap about the benefits and harms of RDM in the PHC setting. It can also help inform equity considerations, by providing information to decision-makers about the benefits and harms of RDM in subgroups and settings, as outlined in the EPOC guidelines for systematic reviews (Welch 2022).

OBJECTIVES

To assess the benefits and harms of remote digital monitoring for adults with selected chronic diseases (hypertension, type 2 diabetes, chronic obstructive pulmonary disease, congestive heart failure, and asthma) in primary healthcare settings.

METHODS

Criteria for considering studies for this review

Types of studies

We will include parallel randomised controlled trials (RCT) reported as full text studies, regardless of language of publication.

To be included, studies must have at least one outcome of interest with between-group data measured at the end of the intervention.

We will exclude cross-over and cluster-randomised controlled trials.

Types of participants

Eligible participants include adults (18 years or older) diagnosed with one or more of the following chronic diseases: hypertension (HTN), type 2 diabetes (T2D), chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), or asthma. We will also consider adults with mental illness as a co-morbidity.

We will include studies in which our populations of interest are a subset, providing the studies provide independent data for each population (i.e. HTN, T2D, COPD, CHF, or asthma).

We will include individuals regardless of country of birth, gender, minority status, socioeconomic status, or ethnicity.

We will exclude children and pregnant women. We suggest a separate review for these populations of interest.

Types of interventions

We will include studies that explore RDM through continuous wireless transmission of biometric data via applications in smart devices with internet connection. This includes data gathered by people with CD, either by manual input of data in the RDM application, or with a wireless connection (e.g. via bluetooth) between the RDM application and sensors (e.g. blood pressure monitor, blood glucose meter, weight scale, activity monitor). People can transfer their data at any time, without restrictions to the number of data inputs. Clinical feedback from the healthcare providers through synchronous (video) or asynchronous (video or text message) communication via RDM application is part of the intervention.

Possible categories for the interventions are:

1. Interventions in which people send self-reports and assessments without clinical feedback.
2. Interventions in which people receive clinical feedback by a telephone call or text (SMS).
3. Interventions with continuous clinical feedback through the person's application connectivity to a digital platform.

We will compare the care delivered by PHC providers using RDM with standard delivery of care. We will define standard care as usual care for the setting in which the study took place, including face-to-face physical, telephone (text message), or ad hoc digital (e-mail, chat, or video) consultation between the PHC provider and the person with CD.

We will assess the quality of the description of interventions in the included studies (e.g. completeness of reporting, replicability) with the template for intervention description and replication (TiDieR) checklist, which provides the minimum recommended items for describing an intervention (Hoffmann 2014).

We will exclude interactive telemedicine interventions not conducted by a RDM application.

Types of outcome measures

We will include the primary and secondary outcomes listed below. Investigating long-term effects of RMD can be determined if the benefits persist over time, and if the use of the technology has a sustained impact on patient health. Dividing the effects into different time periods will provide a more complete and nuanced understanding of the impact of the RMD intervention, and help to inform decisions based on the available evidence. We will categorise the duration of these effects into three time periods:

short-term (1 to 12 weeks), medium-term (13 to 26 weeks), and long-term (> 27 weeks). We will include studies if they report at least one outcome of interest.

Primary outcomes

Participant outcomes, using validated scales, will include:

1. Health status and well-being. When included studies use more than one scale to measure health status and well-being, we will preferentially extract data in this order.
   a. the Short-Form Questionnaire (SF-36 total or the SF-12 total (Busija 2011))
   b. the EuroQol-5D (EQ-5D (EuroQol 1990))
   c. Mini-Cuestionario of Calidad de Vida en la Hipertensión Arterial (MINICHAL (Badia 2002))
2. Quality of care. If included studies use more than one scale to measure quality of care, we will preferentially extract data in this order.
   a. the Quality from the Patient's Perspective (QPP (Larsson 1998))
   b. the Quality from the Patient's Perspective Short form (QPPS (Wilde 2002))
3. Access to services (waiting time to see a nurse or a medical doctor)
4. Hospital admissions (e.g. number of admissions)
5. Hospital length of stay (e.g. number of bed days)
6. Resource use
7. Harm, measured by adverse effects (clinical or other adverse effects (e.g. psychological stress due to the required frequency of data transfers, unnoticed disease exacerbations, or harm caused by non-invasive sensors)).
8. Cost effectiveness of intervention compared to standard care. If included studies use more than one scale or strategy to measure cost effectiveness compared to standard care, we will preferentially extract data in this order.
   a. the number of Quality Adjusted Life Years (QALY (Weinstein 1977))
   b. then the Disability Adjusted Life Years (DALY (Murray 1994))
9. Participant health behaviour
   a. Adherence to treatment. If included studies use more than one scale to measure adherence to treatment or care plans, we will preferentially extract data in this order.
      i. the Morisky scale (Morisky 2008)
      ii. the General Adherence Scale (GAS (Shi 2021))
      iii. the Medical Outcomes Survey-General Adherence Scale (MOS-GAS (Kravitz 1993))
      iv. the A-14 scale (Jank 2009)
      v. the Hill-bone scale (Kim 2000)
   b. Healthcare seeking. If included studies use more than one scale to measure healthcare seeking behaviour, we will preferentially extract data in this order.
      i. the Patient Experiences Survey (PES (Wong 2015))
      ii. the Patient Assessment of Chronic Illness Care (PACIC)-5As scale (Glasgow 2005)
      iii. the Health Information Seeking Behaviour – HISB (Gutierrez 2014)
   c. Self efficacy. If included studies use more than one scale to measure effective self-management, we will preferentially extract data in this order.
      i. the Patient Activation Measure (PAM (Hibbard 2004))
      ii. the Assessment of Chronic Illness Care (PACIC)-5As scale (Glasgow 2005)

Secondary outcomes

1. Participant's acceptability and satisfaction
   a. If included studies use more than one scale to measure acceptability, we will preferentially extract data in this order.
      i. the Technology Acceptance Model (TAM (Davis 1989))
      ii. the Unified Theory of Acceptance and Use of Technology (UTAUT (Venkatesh 2003))
   b. If included studies use more than one scale to measure satisfaction, we will preferentially extract data in this order.
      i. the Net Promoter Score (NPS (Reichheld 2003))
      ii. the Client Satisfaction Questionnaire (CSQ (Larsen 1979))
      iii. the Usefulness, Satisfaction, and Ease of Use (USE (Lund 2001))

Search methods for identification of studies

Electronic searches

The Karolinska Institutet's Library developed an initial draft search strategy, in consultation with the first and second review authors. This draft was discussed with, and adapted by, the Cochrane Effective Practice and Organization of Care (EPOC) Group's Information Specialist, Nia Roberts. We will refine the search following peer review by the Norwegian EPOC satellite Information Specialist, Marit Johansen.

We will search the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL; latest issue), in the Cochrane Library;
- MEDLINE Ovid (1946 to date of search);
- Embase Ovid (1974 to date of search);
- CINAHL EBSCOHost (Cumulative Index to Nursing and Allied Health Literature; 1982 to date of search);
- Science Citation Index and Conference Proceedings Citation Index - Science via Web of Science Core Collection (1900 to date of search);
- Global Index Medicus (https://www.globalindexmedicus.net/; to date of search).

The search strategies are comprised of free-text keywords and controlled vocabulary terms. We will not apply any limits on language. We will limit the search to 10 years (from 2012), applying the same time frame as other EPOC reviews conducted for the WHO.

We will use methodology search filters to limit retrieval to appropriate study designs, e.g. the Cochrane Highly Sensitive Search Strategy (sensitivity-maximizing version - 2008 revision to identify randomised controlled trials (Lefebvre 2022)). See Appendix 1 for the MEDLINE search strategy, which we will adapt for the other databases.

Searching other resources

Trial registries

- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; www.who.int/ictrp; to date of search)
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; to date of search)

Preprints

- Europe PMC (europepmc.org/; to date of search)

Grey literature

We will conduct a grey literature search to identify studies not indexed in the databases listed above.

- Grey Literature Report (New York Academy of Medicine; www.greylit.org; to date of search)
- Agency for Healthcare Research and Quality (AHRQ; www.ahrq.gov; to date of search)
- Joanna Briggs Institute (www.joannabriggs.edu.au; to date of search)
- National Institute for Health and Clinical Excellence (NICE; www.nice.org.uk; to date of search)

We will also review reference lists of all included studies, and relevant systematic reviews identified during the search, for additional potentially eligible primary studies.

We will list all of our search strategies in appendices, including a list of sources screened, and relevant reviews and primary studies reviewed.

Data collection and analysis

The first author is certified in conducting Cochrane Systematic Reviews, and three review authors will be trained in data extraction, using a standardised orientation program. Review authors will work independently and in pairs to extract data and assess the quality of included RCTs. The team will meet regularly to discuss progress, to clarify procedures, to make decisions regarding inclusion or exclusion and classification of outcome variables, and to work collaboratively in the production of this review. All authors declare they have no conflict of interest.

Selection of studies

Pairs of review authors (MT, AJ, JB, PP) will independently examine the titles and abstracts of the reports generated from the searches against the inclusion criteria (Appendix 2). If our literature search generates fewer than 2500 reports, we will use Covidence software to assist with the reference screening (Covidence). If it yields more than 2500 reports, we will use the software EPPI Reviewer for the screening process (EPPI 2022), If using EPPI Reviewer, and to streamline the screening of titles and abstracts, we will use the machine learning function 'priority screening' (Tsou 2020).

We will retrieve the full texts of seemingly relevant reports and publications, and a pair of review authors (MT, AJ, JB, PP) will independently assess these against the inclusion criteria. We will list full-text reports that we read and subsequently excluded, with the reasons for exclusion, in the characteristics of excluded studies table. We will describe studies that meet the inclusion criteria in the characteristics of included studies table, even if they do not report usable results. We will resolve any disagreement through discussion; if required, we will consult an arbitrator (GN, MH, GMF). We will translate non-English reports if needed.

We will collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review (Rosenthal 1995). We will also provide any information we can obtain about relevant trial registry records or published protocols found by the search. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009).

Review authors involved in the conduct, analysis, and publication of a study included in the review, will not be involved in study eligibility decisions, data extraction, or methodological assessment of that study.

Data extraction and management

We will use electronic data collection forms, developed and pilot tested to facilitate independent data extraction and consensus. Pairs of review authors (MT, AJ, JB, PP) will independently extract data from the included studies. Disagreements will be resolved by consensus, or if necessary, by consultation with an arbitrator. Pairs of review authors (MT, AJ, JB) will independently transfer data into Review Manager Web (RevMan Web 2022). In the characteristics of included studies table, we will note if outcome data were not reported in a usable way, instances when data were obtained from RCT authors, and if we had to transform or estimate the data from a graph. If both unadjusted and adjusted values for the same outcome are reported in the RCT, we will extract the adjusted values. If data were analysed based on both an intention-to-treat (ITT) sample and another sample (e.g. per protocol, as treated), we will extract the ITT data. We will extract the following data from the included studies.

1. Methods: study design, number of PHC centres and settings, and geographical location (e.g. country, rural, urban, or a combination), withdrawals, date of study, follow-up, details of any 'run-in' period
2. Participants: number (N), mean age, age range, gender, ethnicity, minority status, socioeconomic status, severity of condition, diagnostic criteria or condition, inclusion criteria, exclusion criteria, other relevant characteristics
3. Interventions: intervention components (e.g. sensor, hub, if data are processed at final destination), comparison components
4. Outcomes: primary and secondary outcomes as outlined above, based on:
   a. means, medians, standard deviations (SD), or confidence intervals (CIs) for tests at baseline, post-intervention, and follow-up assessment(s) for continuous outcomes (e.g. health-related quality of life (HRQoL)); and odds ratios (OR) or risk ratios (RR) for dichotomous outcomes
   b. If post-test data are not available, means and standard deviations of change scores
   c. Numerical or narrative information per group describing adverse events
5. Notes: funding for trial, notable conflicts of interest of trial authors, ethical approval

Assessment of risk of bias in included studies

Pairs of review authors (MT, AJ, JB, PP) will independently assess risk of bias for each study using the RoB 1 criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We will resolve any disagreements by discussion, or by involving an arbitrator (GN, MH).

We will use RoB 1 to assess the risk of bias according to the following domains.

1. Random sequence generation
2. Allocation concealment
3. Blinding of participants and personnel
4. Blinding of outcome assessment
5. Incompete outcome data
6. Selective outcome reporting
7. Other bias

We will judge each potential source of bias as high, low, or unclear, and provide a quote from the study report, together with a justification for our judgement, in the risk of bias table. When a trial registry record or published protocol is available for an included study, we will use it to assess selective outcome reporting, and report it as a companion record. We will synthesise risk of bias assessments by generating risk of bias summary figures using Review Manager Web (RevMan Web 2022).

We will report any deviations from the study protocol in the Differences between protocol and review section of the systematic review.

Measures of treatment effect

We will estimate the effect of the intervention using odds ratio (OR), risk ratio (RR), or risk difference (RD) for dichotomous data, together with the associated 95% confidence interval (CI). For continuous data, we will calculate the mean difference (MD) if the same measurement tool is used for the outcome, or standardised mean difference (SMD) if different tools are used to measure the same outcome, together with the associated 95% CI (Higgins 2022). If the included studies report time-to-event data (survival data), we will extract the log of the hazard ratio (log(HR)) and its standard error (SE) from trial reports. The effects will be analysed as dichotomous data, and expressed as OR, RR, or RD.

We will ensure that an increase in scores for continuous outcomes can be interpreted in the same way for each outcome, explain the direction to the reader, and report where the directions were reversed, if necessary. We will use RevMan Web to generate forest plots to display the results. When evaluating long-term effects, we will group data for analysis into three intervals, starting from the week the intervention ends: short-term (1 to 12 weeks), medium-term (13 to 26 weeks), and long-term duration (> 27 weeks).

In the comments column of the summary of findings table for the main comparison, RDM versus standard care, we will provide the absolute percent difference and the number needed to treat for an additional beneficial outcome (NNTB), or the number needed to treat for an additional harmful outcome (NNTH). We will provide the NNTB or the NNTH only when the outcome shows a clinically important between-group difference. We will calculate the NNTB for continuous measures using the Wells calculator (Wells 2023).

For dichotomous outcomes, we will calculate the NNTH from the control group event rate and the relative risk using the Visual RxNNT calculator (Gates 2008).

Unit of analysis issues

If included randomised trials report data for more than two parallel arms (i.e. groups), resulting in several relevant comparisons, we will examine all relevant comparison of the effects of RDM interventions for individuals with CDs. If a control group is used as a comparator twice in the same analysis, the sample size of the control group will be halved.

An important principle in clinical trials is that the analysis must take into account the level at which randomisation occurred. For parallel designs, the unit of analysis will be the participant.

Dealing with missing data

If numerical data are missing, we will contact investigators to try to verify key study characteristics and request missing outcome data for analysis. We will try to compute missing summary data from other reported statistics. If we are unable to obtain the data, we will report the level of missingness, and consider how it might impact the certainty of the evidence. We will indicate our correspondence with authors in the Notes section of the characteristics of included studies table.

Assessment of heterogeneity

We will use the I^2 and Chi^2 statistics to measure heterogeneity among the trials in each analysis. We will follow the interpretation that an I^2 value from 0% to 40% might not be important; 30% to 60% may representing moderate heterogeneity; higher than 50% may represent substantial heterogeneity; and 75% to 100% represents considerable heterogeneity (Higgins 2022). If we identify heterogeneity above 50%, we will explore it thoroughly. We will remove a trial(s) from the analysis and recalculate both heterogeneity and effect size. In addition, we will assess clinical and methodological diversity in terms of participants, interventions, outcomes, and study characteristics, to determine whether a meta-analysis is appropriate.

If there are sufficient numbers of comparisons for similar outcomes across studies, we will use STATA for graphical displays (e.g. box and whisker plots) to visually explore the heterogeneity of the results across studies (Stata 2020). We will use the I^2 statistic to assess the extent of variability beyond chance for each of the groups of studies assessing similar comparisons and outcomes (Higgins 2003).

Assessment of reporting biases

If there are more than 10 studies available, we will create and examine funnel plots to explore possible publication biases, interpreting the results with caution (Sterne 2011).

We will use a funnel plot to visually explore the risk of publication bias, using the population of the included jurisdictions in each study as a proxy of the precision of the estimate, and the adjusted RR or RD as the intervention effect. When interpreting the results, we will consider other potential causes of funnel plot asymmetry, such as small-study effects (the tendency for the intervention effects estimated in smaller studies to differ from those estimated in larger studies), differences in methodological quality across studies, or true heterogeneity in intervention effects (Sterne 2011).

Data synthesis

If two or more studies are homogeneous enough and report the same outcome and intervention, we will pool the data in a meta-analysis, using RevMan Web (RevMan Web 2022). Trialists often indicate they have skewed data by reporting medians and interquartile ranges. When we encounter this, we will note that the data are skewed and consider the implication of this. For continuous outcomes, before pooling data, we will ensure that the directionality of the data permits pooling. We will ensure that scaling factors are consistent to permit calculation of MD (e.g. 10-cm scales are expressed in mm to match other metric scales).

We will include all studies in the meta-analysis, regardless of their risk of bias. As we anticipate heterogeneity of the interventions, we plan to use a random-effects model for the meta-analysis.

If there is additional outcome information that we were unable to incorporate into meta-analyses, we will note this in the comments, and state if it supports or contradicts the information from the meta-analyses. If it is not possible to meta-analyse the data, we will summarise the results in the text. We will summarise studies that we did not include in the meta-analysis separately, using the SWiM approach (Campbell 2020).

Review authors involved in the conduct, analysis, and publication of a study that could be included in the review, will not be involved in study eligibility decisions, data extraction, methodological assessment, or perform quality assessments for that study.

Subgroup analysis and investigation of heterogeneity

All participant data included in the meta-analysis will be split into subgroups according to:

1. Age (> 18 to 55, and 56 and older)
2. Gender

We will undertake a meta-analysis on these subsets of trials.

We will use quality of life (QoL) as a possible effect modifier in subgroup analyses. QoL is a well validated and broadly used measurement of health among people and has clinical relevance. It can also be considered a proxy for the primary and secondary outcomes in our review, such as participant satisfaction and adherence.

We will apply the characteristics that stratify health opportunities according to the PROGRESS framework to assess the effects of health equity, for example culture, religion, socioeconomic status, and social capital (O'Neill 2014).

We will use formal statistical significance tests of differences (t-test, etc.) to test for subgroup interactions.

Sensitivity analysis

We will undertake sensitivity analyses to assess the robustness of our conclusions and explore its impact on effect sizes. We will restrict the sensitivity analysis to these two major outcomes: hospital admission and cost-effectiveness. This will involve the following:

- only include studies at low risk of bias in the meta-analysis.
- only include data from published studies in the meta-analysis.
- only include data from studies that imputed missing data in the meta-analysis.

A sensitivity test will be done for each study that is included to evaluate the effects of the interventions. There will be no sensitivity analysis according to the language of the studies.

Summary of findings and assessment of the certainty of the evidence

We will use the GRADE approach to assess the certainty of evidence (high, moderate, low, and very low) that supports each of the main outcomes, at the end of the intervention, using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias (Guyatt 2008)). We will use methods and recommendations described in the *Cochrane Handbook for Systematic Reviews of interventions (*Schünemann 2022), and the EPOC worksheets (EPOC 2022). We will use the GRADEpro GDT software to import data from RevMan Web and create the summary of findings tables (GRADEpro GDT; RevMan Web 2022). We will use plain language statements to report these findings in the review (Schünemann 2022).

Two review authors (MT, AJ) will independently summarise the findings in a summary of findings table for the main comparison (between RMD and usual care), for the following six outcomes:

1. Health status and well-being
2. Quality of care
3. Hospital admissions
4. Harm, measured by adverse effects
5. Cost-effectiveness
6. Participant's acceptability and satisfaction

Stakeholder consultation and involvement

It is considered good practice to involve stakeholders in systematic reviews (Pollock 2018).

To promote transparency and accountability, and to address evidence related to the needs of people with chronic diseases, we involved stakeholders in identifying priority review outcomes, and in peer reviewing the draft protocol. The stakeholders involved in this review have the following roles:

People with chronic diseases: Ms Jenny Christensson and Mr. Fredrik Josephson
Role: contributing their expertise to the project with feedback on draft protocol, selection of outcomes, assistance with the plain language summary

Policymaker: Ms Karina Tellinger, Co-ordinator and Strategist at Sweden's municipalities and regions (Sveriges kommuner och regioner (SKR)). Ms Tellinger is an expert in communication and presentation of remote monitoring, interpretation, and information about how it works today, and scenarios for future use in Sweden.
Role: contributing with expertise and feedback on draft protocol, outcome selection, assistance with the plain language summary

All stakeholders are offered an hourly payment of 350 SEK (25 GBP) per hour of their involvement to compensate for the time they spent away from work. We estimate a total of three hours of involvement per stakeholder.

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- Sign-off Editor (final editorial decision): Sasha Shepperd, University of Oxford
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APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to present

1 Chronic Disease/ or Noncommunicable Diseases/

2 exp Comorbidity/

3 exp Hypertension/

4 Blood Pressure Monitoring, Ambulatory/

5 exp Heart Failure/

6 exp Diabetes Mellitus, Type 2/

7 Blood Glucose Self-Monitoring/

8 exp Asthma/

9 exp Pulmonary Disease, Chronic Obstructive/

10 ((chronic or longterm or long-term) adj2 (disease? or disorder? or condition?)).ti,ab,kf.

11 (comorbid* or co-morbid* or multimorbid* or (multiple adj2 (morbidit* or condition* or disorder?))).ti,ab,kf.

12 asthma*.ti,ab,kf.

13 (copd or (chronic obstructive adj2 (lung or pulmonary or airflow or airway?)) or emphysema).ti,ab,kf.

14 (((type 2 or type ii or noninsulin dependent or non-insulin dependent or adult onset or maturity onset or mature onset) adj2 diabet*) or niddm or mody).ti,ab,kf.

15 diabet*.ti.

16 (bgsm or ((blood glucose or h?emoglobin a1c or glycated h?emoglobin or hba1c or hb a1c) adj2 (selfmonitor* or monitor* or measure* or selfmanag* or self-manage*))).ti,ab,kf.

17 (hypertens* or ((blood pressure or bp) adj2 (selfmonitor* or monitor*))).ti,ab,kf.

18 ((heart or cardiac or myocardi*) adj2 (failure or insufficiency)).ti,ab,kf.

19 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18

20 Primary Health Care/

21 general practice/ or family practice/

22 general practitioners/ or physicians, family/ or physicians, primary care/

23 exp Community Health Nursing/ or Nurses, Community Health/

24 Community Health Services/

25 home care services/ or home health nursing/ or home nursing/

26 exp rural health services/ or urban health services/

27 Community Health Centers/

28 ((primary or community) adj2 (care or healthcare)).ti,ab,kf.

29 (((general or family) adj2 (practi* or physician? or doctor?)) or gp or gps).ti,ab,kf.

30 (community adj2 (centre? or center? or clinic? or service?)).ti,ab,kf.

31 ((health* or medical) adj (center? or centre? or clinic?)).ti,ab,kf.

32 (((community or family or home) adj2 nurs*) or district nurs*).ti,ab,kf.

33 (home adj2 (care or healthcare or service? or visit?)).ti,ab,kf.

34 ((rural or urban) adj2 (health* or care or service?)).ti,ab,kf.

35 ((rural or urban) adj2 (population? or communit* or neighbo?rhood?)).ti,ab,kf.

36 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35

37 Telemedicine/ or Remote Consultation/

38 telemetry/ or remote sensing technology/

39 Biosensing Techniques/

40 exp Cell Phone/

41 Mobile Applications/

42 Wearable Electronic Devices/

43 Wireless Technology/

44 Videoconferencing/

45 "Internet of Things"/

46 Computer Communication Networks/ or Internet/

47 Internet-based Intervention/

48 (telemetr* or tele-metr* or telemonitor* or ((remote or tele* or home*) adj3 monitor*)).ti,ab,kf.

49 (telemed* or tele-med* or telehealth or tele-health).ti,ab,kf.

50 (teleconsult* or tele-consult* or ((video* or virtual or telephone? or phone?) adj3 (consult* or visit* or appointment? or conferenc*)) or videoconferenc* or skype or zoom).ti,ab,kf.

51 (tele* adj2 assist*).ti,ab,kf.

52 (ehealth or e-health or mhealth or m-health or mobile health).ti,ab,kf.

53 ((mobile adj2 (app* or device? or technolog*)) or app or apps).ti,ab,kf.

54 (cellphone? or cell phone? or mobile phone? or textmessag* or text-messag* or short messag* service? or sms or multimedia messag* service? or multi-media messag* service? or mms or smartphone? or smart phone? or iphone? or smartwatch* or smart watch* or apple watch* or tablet or ipad? or smarthome? or smart home?).ti,ab,kf.

55 (IOT or "internet of things").ti,ab,kf.

56 (biosensor? or bio-sensor? or biosensing or bio-sensing or bioprobe? or bio* probe? or intelligent sensor? or wearables or (wearable adj3 (device? or monitor* or technolog* or sens*))).ti,ab,kf.

57 (remote adj3 (device? or technolog* or sens*)).ti,ab,kf.

58 ((online or digital or wireless or wifi or bluetooth or internet or mobile or remote) adj3 platform?).ti,ab,kf.

59 ((((ambulatory or physiological or physical or vital sign? or respiratory or respiration or breath* or heart or pulse) adj5 (selfmonitor* or monitor* or measure* or selfmanag* or self-manage*)) or oximet*) and (online or digital or wireless or wifi or bluetooth or internet)).ti,ab,kf.

60 ((titrat* or selftitrat* or ((dose* or dosage* or drug? or medic* or pharmaceutical?) adj3 adjust*)) and (online or digital or wireless or wifi or bluetooth or internet)).ti,ab,kf.

61 ((online or digital or wireless or wifi or bluetooth or internet) adj2 (transfer* or transmi*)).ti,ab,kf.

62 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61

63 randomized controlled trial.pt.

64 controlled clinical trial.pt.

65 Pragmatic Clinical Trial.pt.

66 randomi?ed.ab.

67 placebo.ab.

68 drug therapy.fs.

69 randomly.ab.

70 trial.ab.

71 groups.ab.

72 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71

73 exp animals/ not humans.sh.

74 72 not 73

75 19 and 36 and 62 and 74

76 limit 75 to yr="2012 -Current"

Appendix 2. Screening criteria

Level one screen

Based on the title and abstract of the report:

1. Does the study deal with digital transmission of biometric data and clinical feedback between patients and their health care provider? No – exclude, Yes – or Uncertain – go to step two
2. Does the study deal exclusively with a primary healthcare setting, including home care? No – exclude, Yes or uncertain – go to step two
3. Does it include chronic patients with any of the following diagnosis: hypertension, type 2 diabetes, chronic obstructive pulmonary disease, congestive heart failure, asthma? No – exclude, Yes or uncertain – go to step two
4. Does the study deal with adults? No – exclude, Yes or uncertain – go to step two
5. Is it an RCT (the study uses terms such as 'random', 'randomized', 'RCT', or 'randomization' to describe the study design or assignment of subjects to groups)? No – exclude, Yes or uncertain – go to step two
6. Is the publication year after 2012? No – exclude, Yes or uncertain – go to step two

Level two screen

Based on the full text of the report or protocol:

1. Does the study deal with adults? Yes – include. If entire population age is under 18, exclude. If mixed group, then report adult group separately for the study to be included.
2. Does the study deal exclusively with a primary health care setting, including home care? No – exclude, Yes – include, uncertain – add to list of questions for authors
3. Does it include at least one intervention of remote clinical feedback from healthcare providers, based on electronically transferred biometric data from patients? No – exclude, Yes – include, Uncertain – add to list of questions for authors
4. Are data provided for the outcomes in both the intervention and control group? No – exclude, Yes – include the study, Uncertain – reserve judgement until authors are contacted
5. Is it an RCT (the study uses terms such as 'random', 'randomized', 'RCT', or 'randomization' to describe the study design or assignment of subjects to groups)? No – exclude, Yes include
6. Does it include chronic patients with any of the following diagnosis: hypertension, type 2 diabetes, chronic obstructive pulmonary disease, congestive heart failure, asthma? No – exclude, Yes – include, Uncertain – add to list of questions for authors

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Conceiving the protocol: MT, AJ

Designing the protocol: MT, AJ, JB

Co-ordinating the protocol: MT, AJ

Designing search strategies: NR, MT, AJ, PP

Writing the protocol: MT, AJ

Providing general advice on the protocol: JB, GN, MH, GF

Securing funding for the protocol: N/A

Performing previous work that was the foundation of the current study: N/A

DECLARATIONS OF INTEREST

- Marina Taloyan: none known
- Alex Jaranka: part time PhD student and part time Chief Medical Officer at Cuviva AB. In my role in Cuviva AB, I serve as medical advisor to align Cuvivas' service to patient and clinical perspectives. Cuviva AB does not provide services that will be assessed within the full review, nor has randomised controlled trials or scientific publications that will be included in the full review. Cuviva AB does not fund my research in any way, nor does it fund my involvement with the Karolinska Institutet or Academic Primary Healthcare Centre (APC). Cuviva AB has no financial attachments to the Karolinska Institutet or APC in any other way.
- Julia Bidonde: none known
- Gerd Flodgren: none known
- Maria Hägglund: none known
- Gunnar Nilsson: none known
- Panagiotis Papachristou: none known

Review authors involved in the conduct, analysis, and publication of a study that could be included in the review, will not be involved in study eligibility decisions, data extraction, methodological assessment, or perform quality assessments for that study.

SOURCES OF SUPPORT

Internal sources

- Karolinska Institutet, Sweden

  Statistician
- Cochrane: information specialist, UK

  Peer review of search strategy: Marit Johansen

External sources

- Monash University, Monash Department of Clinical Epidemiology - Cabrini, Australia

  Infrastructure support
- Karolinska Institutet University Library, Sweden

  Search strategy and advice on terminology

NOTES

This protocol is based on standard text and guidance provided by Cochrane Effective Practice and Organisation of Care (EPOC).