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Factors influencing effectiveness of remote patient monitoring interventions: A realist review

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Abstract (258 words)

Objectives: Remote patient monitoring (RPM) is an underutilised telehealth intervention that can enhance self-management of chronic disease and reduce acute care use. However, effectiveness of RPM interventions varies within and between populations. This study aimed to explain the variation in outcomes related to RPM interventions.

Design: Systematic search and realist review

Participants: A systematic literature review was undertaken for studies published from January 2015 to October 2020 reporting RPM and effect on hospitalisations, length of stay, or emergency department presentations. All populations and disease conditions were included.

Primary and secondary outcome measures: Realist review methodology was used to evaluate 91 studies that reported on RPM interventions and the impact on acute hospital use. Outcomes were evaluated to determine contextual factors and potential mechanisms that led to variation in outcomes of acute hospital use.

Results: We found that across a broad range of RPM interventions 31 factors emerged that are likely to impact the effectiveness of RPM innovations. These were synthesised into six theories of intervention success: 1) targeting populations at high risk; 2) accurately detecting a decline in health; 3) providing responsive and timely care; 4) personalising care; 5) enhancing self-management and, 6) ensuring collaborative and coordinated care.

Conclusion:

While RPM interventions are complex, if they are designed with patients, providers and the implementation setting in mind and with the key variables identified within this review incorporated, it is more likely that they will be effective at reducing acute hospital events.

Registration: The protocol for our review was registered (#CRD42020142523) with the Prospective Register of Systematic Reviews (PROSPERO).

Strengths and limitations

- Our review was strengthened by a comprehensive search and inclusivity of diverse RPM interventions across a broad spectrum of conditions and contexts.
- The novel use of realist review methodology and development of theory-based constructs helped to systematically identify factors impacting upon implementation.
- Included studies within our review had multiple study design issues. Typically, with many of these studies it is not possible (or ethical) to blind participants. Therefore, selection bias may have effected results if health professionals pragmatically selected more willing or engaged patients to participate in the trials.
- While our focus was on acute care use, other aspects of care may have been overlooked that relate to care quality.

Introduction

Non-communicable diseases such as heart disease, chronic obstructive pulmonary disease (COPD), and diabetes accounts for over 70 per cent of global deaths each year.[1] Combined with the added challenge of ageing populations, health systems internationally are under enormous strain to support growing numbers of chronically unwell people.[2] One of the main drivers of healthcare costs for chronically ill patients results from acute hospital admissions due to their intense resource requirements.

Remote patient monitoring (RPM) is a telehealth innovation that offers significant opportunities to increase the timeliness of care, enhance health outcomes, and potentially reduce hospitalisations and associated healthcare costs.[3, 4] RPM uses technology to observe a patient's physiological (e.g. heart rate, blood pressure) and behavioural (e.g. medication adherence, physical activity) information from a distance.[5] With support, many individuals could effectively self-manage chronic conditions in the community.[6] Further, if alerted early, healthcare providers could intervene when a person's health is declining, potentially preventing costly escalations to hospital. Health professionals can routinely monitor a patient's health data and/or be alerted when measurements exceed a pre-determined threshold. This allows for early intervention and ideally prevention of further exacerbation of a condition. RPM can benefit people with chronic illness as well as other population groups that benefit from continuous monitoring such as the frail and elderly, neonates or post-surgical patients.[5]

Despite the potential benefits of RPM, investigations into its clinical and cost effectiveness have provided mixed results to date. For example, the impact of RPM on the heart failure population has resulted in multiple systematic reviews[7], meta-analyses[8, 9], and reviews of reviews.[10, 11] These reviews are generally positive about the potential benefits for patients and health services from RPM services,[7, 8, 10, 12] but others also report limited or no effect[9] on reducing morbidity and mortality. A 2018 Cochrane review reported no difference in all-cause mortality in remotely monitored patients with heart failure and a change in hospitalisations ranging from a 64% decrease to a 60% increase.[9] In our recent review[13], we provided a synthesis of the available evidence for the effect of RPM on acute care use including hospital admission events, hospital length of stay, and emergency department presentations. We found that RPM was reported to reduce acute care use in approximately 45% of studies. Remaining studies largely reported no change; however, some reported an increase in acute care use. The included 91 studies covered multiple chronic conditions, countries and health care organisations and used various technology and models of care. While RPM can have a positive impact on patient outcomes, certain enables are needed. Clinicians, researchers, and policymakers require more guidance on how to design and implement RPM-facilitated models of care to achieve the greatest benefit. Consequently, further analysis is required to understand underlying mechanisms causing such variation in RPM interventions.[14]

We sought to understand what causes variation in outcomes from RPM interventions. While our original review was able to determine the observed effect of RPM on acute care use, we further analysed the existing evidence to try to explain why these effects were observed. Specifically, this study aims to (1) identify factors of RPM interventions that relate to increased and decreased acute care use, and (2) develop recommendations for future RPM intervention design and implementation.

Methods

To achieve the aims of this study we reviewed the same 91 articles included in our recent RPM systematic review, using realist review methodology to identify factors that determine intervention success and failure in various contexts.[13] Realist review methodology enables exploration of how, why and for whom interventions do and do not work. The basic tenant of realist philosophy is that the effectiveness of an intervention is impacted by the context in which it is implemented which will trigger mechanisms that result in intended and unintended outcomes.[15] Realist reviews are particularly helpful for complex interventions like RPM interventions where the effectiveness is impacted by multiple interacting components such as the intervention design, users, interpersonal relationships and institutions and settings where the intervention is delivered. This review was guided by the work of Pawson et al (2005)[16] and followed guidelines outlined by the Realist and Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES; Appendix A)[17].

We used data from our recent systematic review that compared acute care use between individuals who were and were not monitored using RPM. In brief, search terms for remote monitoring and acute care utilisation were used across three electronic databases: PubMed (MEDLINE)[1966-2020], EMBASE (OvidSP)[1974-2020], and CINAHL (EBSCOHost)[1982-2020]. The search, conducted in October 2020, included articles published in the last five years (2015-2020). Articles were included if they used RPM to monitor an individual's biometrics (e.g. heart rate, blood pressure) from a distance while they are not in hospital. No restrictions were placed on patient age, or disease conditions however full-text studies had to be available in English. Complete details of the original systematic review have been described elsewhere.[13]

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Evidence synthesis

According to the methodology described by Pawson et. al.[16] information was extracted that related to context (settings, populations, intervention delivery); outcomes (positive, negative or null effect on outcome of hospital use), and potential mechanisms or reasons behind the results (e.g. author's interpretation as to why the interventions did or did not work). These data were recorded in an Excel spreadsheet to facilitate a structured analysis. Two researchers (ET, MT) independently extracted this data.

The researchers then collectively examined the articles to detect patterns and developed a compendium of explanatory factors observed in the RPM studies. The researchers compared and discussed their identified factors that led to increased or decreased acute care use being reported in the studies. Findings were then combined into a table showing the number of studies proposing each mechanism and grouped by outcome (e.g. increased or decreased acute care use).

The two researchers then jointly mapped recurrent patterns into explanatory context-mechanism-outcome (CMO) diagrams to illustrate how the different factors interact. Literature was also examined for opposing or conflicting viewpoints. These CMO diagrams were discussed with a third member of the research team (LC) to confirm consistent and logical development. Key findings were synthesised into overarching themes, which are referred to as 'theories' in the realist review approach.[16] Finally, a list of recommendations was developed from the findings and ordered by context to guide future RPM intervention design and implementation.

Results

Ninety-one articles from our previous review were evaluated to determine why RPM increased, decreased, or had no effect on acute care use. Thirty-one factors were identified and mapped onto two outcomes: 1) increased hospital use (21 factors) and 2) reduced hospital use (10 factors) (Figures 1 & 2). Factors were also ordered by the frequency of articles that reported them as possible influences on outcomes (represented by the size of each factor in Figure 1 and 2).

[Insert Figure 1]

Figure 1 *Factors associated with RPM intervention studies that reduced acute care use.*

The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.

CIED: Cardiac implantable electronic devices; Pt: patient; RPM: remote patient monitoring

[Insert Figure 2]

Figure 2 *Factors associated with RPM interventions studies that increased acute care use.*

The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.

RPM: remote patient monitoring; Pt: patient

Theories about how RPM works

It was identified that successful RPM interventions, in this case those interventions that successfully reduced acute care use, were those that: 1) *target populations at high risk;* 2) *accurately detect a decline in health; 3)* were *responsive* and *provided timely care; 4) provided personalised care;* 5) *enhanced self-management* and, 6) *ensured collaborative and coordinated care*. Each of these theories of intervention success are described below.

Target populations at high risk

Appropriate selection of patients for RPM is crucial if a change in acute care use is to be achieved. RPM interventions are likely to have more pronounced effects on acute care use when they are targeted towards populations with a high risk of hospitalisation (e.g. moderate-severe disease severity, multiple comorbidities).[18] Further, it is important for the intervention to be timed with periods of high-risk readmissions (e.g. the first 90 days post an index event). Delaying the delivering of RPM devices to patients may reduce the effect.[19]

Patients who are more likely to present to hospital multiple times have a greater chance of reducing admissions due to more timely interventions. In practice, however, clinicians may have reservations about remotely assessing their most vulnerable and unwell patients. As described by Geller et al.,[20] *"in clinical practice telemedicine seems to be used mainly in patients with better prognosis, probably due to the belief that those who live longer may receive more (i.e. prolonged) benefit from*

telemonitoring than sicker patients who should be seen in the office more frequently" (pg. 1124). Consequently, clinicians may require additional information on how RPM can be safely delivered in high-risk cohorts.

[Insert Figure 3]

Figure 3. *Proposed context-mechanism-outcome:* ***target population***

Accurately detect a decline in health

RPM needs to accurately predict disease exacerbations by detecting a change in symptoms that relate to health deteriorations. This has been a challenge in certain populations such as COPD and heart failure patients which may have unpredictable disease progression. In the COPD population, multiple studies reported trying to determine the measurement (e.g. spirometry, oximetry, or a combination) which would mark the onset of an exacerbation,[21-24] however, none came to a definitive conclusion.[25] RPM can be used in these population groups to longitudinally track the progression of disease and develop parameters to be tested as predictors for future interventions.[26]

In the heart failure population, physiological signs may not provide adequate warning of decompensation. Readmission in this cohort can be a complex interplay of multiple factors and is often not solely limited to physiological variables.[27] If deterioration occurs too quickly, there is limited opportunity to intervene.[28] Therefore, more investigation is required to try and accurately predict health declines for individual patients and accurately pin-point the best way for RPM to be used to support this patient population.

Implantable devices (e.g. pacemakers) have an additional advantage; continuous monitoring enables undiagnosed co-morbid conditions such as atrial fibrillation to be detected enabling pre-emptive intervention.[29] It can also improve the efficiency of outpatient clinical care by detecting device or lead malfunctions earlier.[30]

Provide timely care via a responsive system

Any benefit from RPM is dependent on patients 1) using the system (e.g. timely data entry) and, 2) providers taking appropriate and equally timely action when out-of-range readings occur.[29] Therefore, RPM systems that use automated data entry wherever possible are preferable as they can reduce errors and delays due to manual entry. As technology improves, smartphone-based programs are likely to replace standard RPM equipment which may result in more consistent, accurate and timely data from patients.[18] For innovations that rely on manual data entry, RPM innovations need to be easy to use (e.g. enables efficient data entry, transportable) and useful for patients to ensure long term use and engagement.[31] Additionally, regular monitoring is required. For example, Srivastava et al.[18] routinely monitored data for abnormalities or lack of responses; if a patient did not submit data for three days, a call was initiated by nursing staff.

On the staff end, RPM alerts need to be actioned with timely and appropriate responses; the speed of decision-making and frequency of monitoring is paramount.[32] A fast response often requires frequent contact with patients and effective bi-directional communication pathways between staff

and patients. For example, Trucco et al.[33] facilitated communication between families and the on-call team via a dedicated phone number or email address. Multiple studies report the importance of dedicated care (e.g. providing an RPM nurse or dedicated case manager) in improving response time.[32, 34-37] This is supported by the literature with findings that patients who received either basic or intensive case management spend less time in hospital than those without.[38] "Fast tracked" access to primary care providers was used in the intervention reported by Pedone et al.[39] when abnormalities were presented, or new symptoms arose. They reported that a new model of care, rather than simply implementing a new technology, was required to obtain sizable benefits in terms of hospitalisation outcomes.[39] Where possible, RPM should be embedded into the system and provide seamless interaction between patients and the healthcare system with minimal encumbrance on both ends.[18]

[Insert Figure 4]

Figure 4. *Proposed context-mechanism-outcome:* ***timely care***

Provide personalised care

Providing a patient-centric and personalised approach was also an important factor in determining the success of an RPM intervention in reducing acute care use.[18] Firstly, the development of the RPM innovation needs to be co-designed with patients and their families to ensure it meets their needs and maximise acceptance and uptake.[40] Training patients on how to use the device will likely also need to be personalised and at times repeated. RPM alerts can also be personalised by using individual data to determine alert thresholds. Koelher et al.[41] recommended defining a risk category for each individual patient based on their positive results (derived from biometric data). One study author requested personalised parameters and treatment guidelines from each patient's treating physician.[42] Determining appropriate parameters for RPM applications (personalised or not) enables the treating team to be alerted to any biometric measurements that fall outside of the personalised parameter ranges. To enable these personalised parameters to be developed physicians need to be engaged in the RPM process for their patient early. The response by the RPM monitoring team also needs to be tailored; considering the person's medical, social and emotional needs.

Enhance self-management

To successfully reduce acute care use, RPM interventions should include support and education to increase self-management skills. Through developing knowledge, skills and positive behaviours (e.g. medication adherence), patients are more likely to be able to effectively manage their condition with the aid of RPM.[43] Additionally, increased awareness of signs and symptoms of disease progression that often occurs when patients use RPM can prompt them to contact their healthcare provider for timely management.[43] Providing feedback from RPM data in a way that empowers patients to take control of their own health is important. Koelher et al.[41] reported that this needs to be a comprehensive approach including education and patient involvement when developing management strategies. In some instances, RPM interventions were discontinued once patients were able to correctly correlate their personal symptoms and seek help when required.[42] Conversely, some RPM interventions that were unsuccessful in reducing hospitalisation events

reported patients becoming overly reliant on the RPM team, for instance alerting the team know when an issue arose rather than developing autonomous self-management skills for their condition. Additionally, some known important factors such as medication adherence were not always measured and present a lost opportunity in many RPM innovations. Medication adherence and timely changes to medications are reported to confer substantial benefits for patients.[41]

[Insert Figure 5]

Figure 5. *Proposed context-mechanism-outcome:* ***self-management***

Ensure collaborative and coordinated care

Successful RPM studies demonstrated increased connection and communication between healthcare staff and patients.[30] Multidisciplinary team-based interventions that combine feedback (automated and/or provider-initiated) with other approaches (e.g. coaching, motivational interviews, and shared decision-making) are more likely to result in improvement in adherence.[44] Involvement of primary care is crucial. As high-risk patients are often managed by primary and specialty care, both hospital and primary care settings should be involved in RPM interventions.[45] Involvement of key stakeholders is required to improve continuity of care.[46] Beyond healthcare professionals, the RPM intervention should also aim to include families and carers as key stakeholders in the long-term management of the person's condition. To increase primary carers' acceptance of and adherence to RPM, they must be involved very early on. To institute an initial change of role, staff incentives (e.g. financial payments) may be required.[26] Additionally, nursing staff should be considered as having leading roles in RPM interventions.[47] Further, institutional support is required for these initiatives and reorganisation of care processes should be carefully planned and implemented.[47]

Factors that resulted in increased acute care use

A range of factors were identified as having influence on hospital use (increasing admissions) and subsequent negative clinical outcomes. For example, multiple study authors reported slow alert response times (N=6)[31, 48-52] and low patient or clinician adherence (N=11) [18, 19, 27, 31, 44, 53-58] as important factors resulting in no change or an increase in acute care use in the RPM group. There also appears to be a delicate balance between providing a supportive environment that empowers patients to self-manage versus having patients become reliant on the RPM device and/or the monitoring team.

Recommendations for RPM

We synthesised multiple recommendations to assist in the design and implementation of RPM interventions (Figure 6).

When designing RPM devices, it is crucial that the measured biometrics accurately predict disease exacerbations. Alert thresholds need to be carefully determined to ensure they are sensitive to physiological changes without being too high, and where possible tailored to the patient and disease

state. Further, the transmission of data needs to be reliable, and if possible, automatic.

It is essential that RPM devices are co-designed with consumers and providers to improve usability and engagement with the RPM system. It is likely that making the device interactive and building in feedback loops between the patient and clinician will enhance engagement. However, if this increases the provider's workload it may discourage provider engagement. Multidisciplinary team interventions that combine feedback with other approaches like patient education, motivational interviewing, coaching or shared decision-making are likely to be more effective long-term.[59]

At the organisation level, having dedicated professionals responsible for monitoring data and communicating with patients and the healthcare team can improve the timeliness and coordination of care. Studies with nursing staff in these leading and case-management roles appeared to be more effective.[47] RPM also needs to be embedded into the health system to provide seamless interaction between patients and the healthcare system. This may require reorganisation of care and additional resources (physical and personnel) to support the intervention.

[Insert Figure 6]

Figure 6*. Recommendations to enhance RPM and reduce acute care use*

Discussion

We found that RPM interventions were successful at reducing acute care use when they incorporated a number of elements including; accurately predicting a decline in health or disease exacerbation, timely response to alerts, personalised patient parameters, and a focus on enhancing patient self-management. Additionally, RPM needed to improve the continuity of care by enhancing collaboration between specialists and primary care. To the best of our knowledge, this is the first review to elucidate why some RPM interventions are more successful than others in reducing acute care use.

RPM interventions are complex because they typically involving multiple components (e.g. data collection, education, feedback) and various stakeholders across different settings (e.g. community, primary and tertiary care). Given the complexity of RPM interventions, it is perhaps unsurprising that RPM studies have resulted in so much variation in the effects demonstrated regarding changes in acute care use. To date, much of the focus of RPM innovations has been on the design and development of the technology.[60, 61] While functioning technology that accurate detects a decline in health is important, to deliver significant benefits RPM alerts must also lead to an actionable and timely responses. To achieve positive results at the healthcare system level, RPM interventions require a change to the *model of care* rather than simple technology implementation.[62]

To be successful, the right patients need to be recruited at the right time. Patients with greater disease severity and at high risk of readmissions appear to confer the greatest benefit of RPM interventions in terms of reduced hospitalisation.[63] For instance, a recent consensus statement from the Heart Failure Society of America[64] broadly concluded that heart failure RPM had the most impact when patients were most at risk (e.g., recent hospitalisation, prone to fluid overload, and struggles with medication adherence). Additionally, RPM should target patients who are willing and likely to adhere with RPM regimes. Huygens suggests there is a relationship between perceived disease

controllability and patients' willingness to self-monitor.[65] Patients with diabetes, asthma and hypertension were most willing to self-monitor. In contrast, patients with rheumatism, migraines and other neurological disorders were less willing. The intervention design can facilitate engagement and use. Hong and Lee[63] determined that interventions with an educational component such as self-management programs have greater effects. Another consideration is the patient's social circumstance. One study found that RPM significantly improved outcomes for socially isolated patients,[66] potentially due to the delay in care access that these patients may face. Conversely, for socially connected patients, outcomes appear to be enhanced by training caregivers.[28, 67]

In primary care, tailoring advice and monitoring symptoms or exacerbations by keeping logs are key self-management support strategies which are routinely used (i.e. food and blood sugar diaries for diabetics).[68] The use of RPM can enhance tailored self-management strategies by providing and visualising data to explain the impact of an individual's health behaviour on their vital signs. This can improve a patient's understanding of why and how they need to modify their behaviour.[59] Patients with low levels of health literacy have the most to gain in improving their self-management knowledge and skills with such interventions. Interventions based on health behaviour models and personalised coaching were most successful.[69] The findings of this review parallel some of the themes in a review of patient experiences of RPM by Walker et al.[70] Similarly, self-management and early identification of clinical exacerbations were key to preventing hospitalisation. From the patient perspective, self-management was achieved by increasing confidence and providing a sense of safety. Shared decision making was identified as a key mechanism to preventing hospitalisation.

Patients have previously reported concerns about being lost in the data or losing interpersonal connections with health professionals and a reluctance to try something new, especially if unfamiliar with technology.[70] Our findings substantiate the importance of co-designing RPM interventions with consumers to ensure they are easy to use and provide useful feedback to maintain adherence and engagement. Building rapport, providing training (sometimes multiple times) and having a two-way interactive relationship between the patient and the RPM team is crucial.

Included studies within our review had multiple study design issues. Typically, with many of these studies it is not possible (or ethical) to blind participants. Therefore, selection bias may have effected results if health professionals pragmatically selected more willing or engaged patients to participate in the trials. However, in real-world clinical settings it is likely (and appropriate) that participants are provided with options regarding their follow-up care. The observer or Hawthorne effect[71] may be at play with participants potentially acting differently due to a belief that they are being watched. Such an effect may reduce with time, and some trial lengths may have been too short for this effect to wear off.

Our review was strengthened by a comprehensive search and inclusivity of diverse RPM interventions across a broad spectrum of conditions and contexts. The novel use of realist review methodology and development of theory-based constructs helped to systematically identify factors impacting upon implementation. However, while our focus was on acute care use, other aspects of care may have been overlooked that relate to care quality. Further, it is possible that reducing hospital admissions may shift care and associated costs to the primary care setting and potentially resulting in additional pressure and stress on different aspects of the system. Additionally, the theories that have been developed are based on both our and the primary study authors' interpretation of findings in many instances and not experimental evidence. Future studies should investigate any unintended consequences of RPM and cost implications resulting from the shifting of care.

Conclusion

RPM interventions have the potential to reduce acute care use when they are targeted to appropriate populations and disease states, designed well, and implemented with patients and providers in mind. This review has highlighted important considerations for developing effective RPM devices, systems and revised models of care. To achieve significant changes in acute care use, RPM data needs to be routinely entered and checked, automated where possible, alerts need to accurately highlight when a person's data is beyond an acceptable range (for that person), and healthcare staff need to respond in a timely and appropriate manner. Further, information and feedback needs be provided to patients in a way that empowers them to self-manage their condition. If designed with these considerations in mind, RPM interventions are more likely to be effective at reduce acute care use.

List of abbreviations

COPD: chronic obstructive pulmonary disease; CMO: context-mechanism-outcome; PROSPERO: Prospective Register of Systematic Reviews; RAMESES: Realist and Meta-narrative Evidence Synthesis: Evolving Standards; RPM: Remote patient monitoring.

Declarations

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Consent for publication: All authors consent to publication

Availability of data and materials: Not applicable

Competing interests: None to declare

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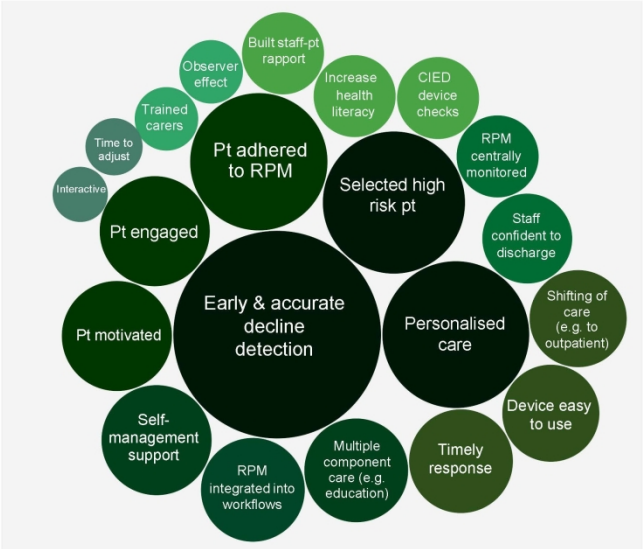

Figure 1 Factors associated with RPM intervention studies that reduced acute care use.
The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.
CIED: Cardiac implantable electronic devices; Pt: patient; RPM: remote patient monitoring

364x215mm (192 x 192 DPI)

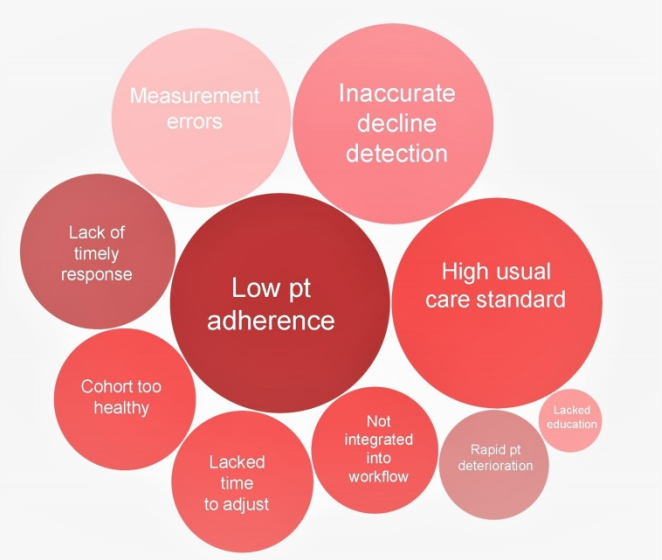

Figure 2 Factors associated with RPM interventions studies that increased acute care use.
The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.
RPM: remote patient monitoring; Pt: patient

728x431mm (96 x 96 DPI)

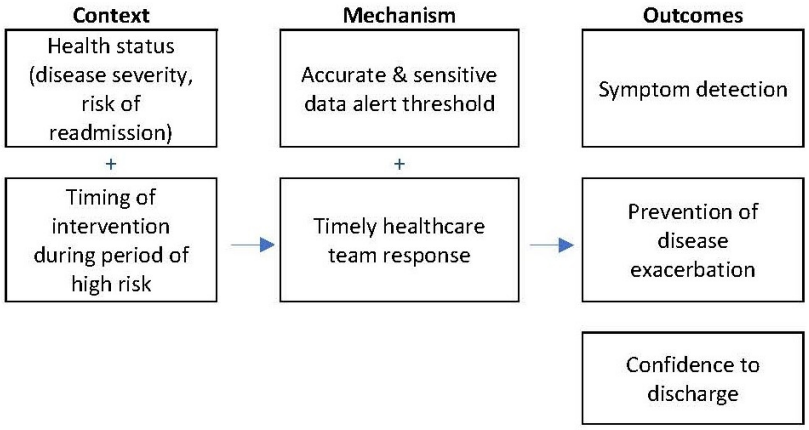

Figure 3. Proposed context-mechanism-outcome: target population

310x171mm (96 x 96 DPI)

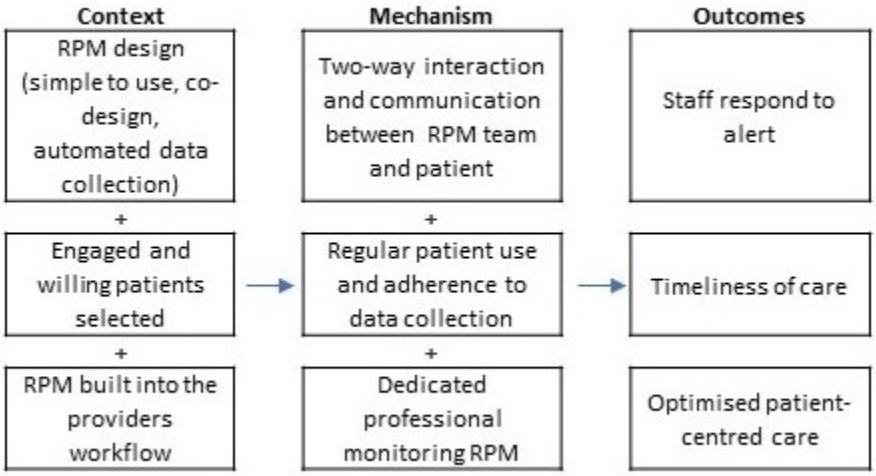

Figure 4. Proposed context-mechanism-outcome: timely care

121x72mm (96 x 96 DPI)

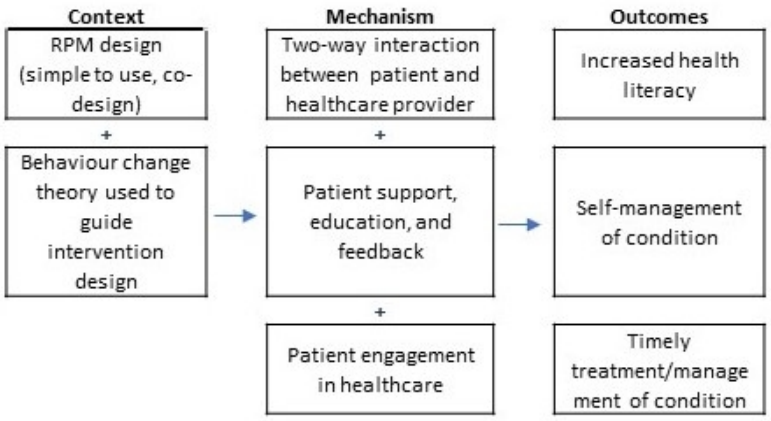

Figure 5. Proposed context-mechanism-outcome: self-management

150x87mm (96 x 96 DPI)

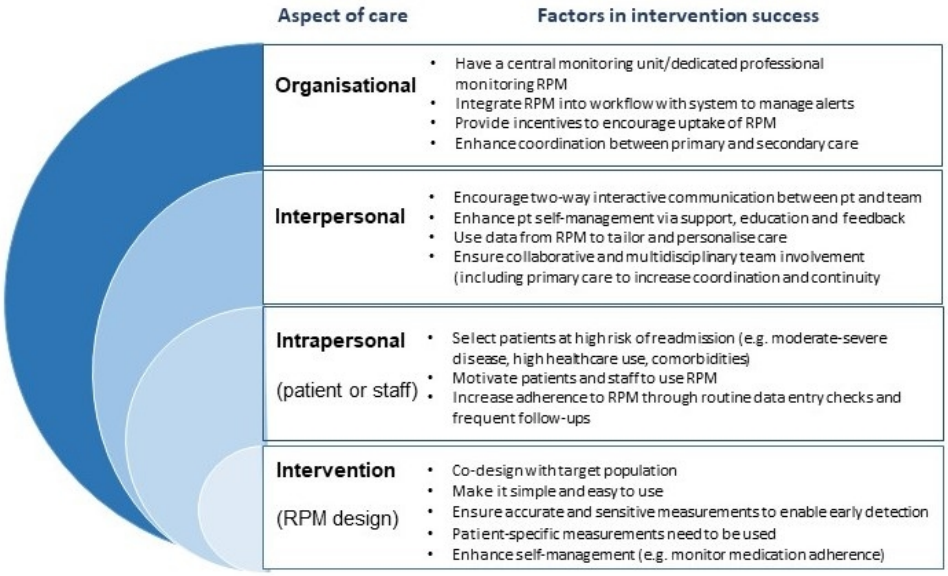

Figure 6. Recommendations to enhance RPM and reduce acute care use

192x128mm (96 x 96 DPI)

Appendix A

RAMESES publication standards: realist synthesis

Wong, G., Greenhalgh, T., Westhorp, G. *et al.* RAMESES publication standards: realist syntheses. *BMC Med* **11,** 21 (2013). https://doi.org/10.1186/1741-7015-11-21

TITLE			**Pg No.**
1		In the title, identify the document as a realist synthesis or review	1
ABSTRACT			
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	2
INTRODUCTION			
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	3
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	3
METHODS			
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.	N/A

TITLE			Pg No.
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.	4
7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.	4
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	4
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these.	4. also additional details provided in previously published paper
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.	As above
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.	As above
RESULTS			
12	Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider	This paper included articles from a previously published review that followed the PRISMA guidelines – the flow

TITLE			Pg No.
		using the example templates (which are likely to need modification to suit the data) that are provided.	diagram is published within that paper.
13	Document characteristics	Provide information on the characteristics of the documents included in the review.	4-8
14	Main findings	Present the key findings with a specific focus on theory building and testing.	4-8
DISCUSSION			
15	Summary of findings	Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).	9
16	Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.	10
17	Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.	9-10
18	Conclusion and recommendations	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	10/11
19	Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers.	1

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Factors influencing effectiveness of remote patient monitoring interventions: A realist review

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Abstract (258 words)

Objectives: Our recent systematic review determined that remote patient monitoring (RPM) interventions can reduce acute care use. However, effectiveness varied within and between populations. Clinicians, researchers, and policymakers require more than evidence of effect; they need guidance on how best to design RPM interventions. Therefore, this study aimed to explore these results further to (1) identify factors of RPM interventions that relate to increased and decreased acute care use, and (2) develop recommendations for future RPM intervention design and implementation.

Design: Realist review - a qualitative systematic review method which aims to identify and explain why intervention results vary in different situations. We analysed secondarily the ninety-one studies included in our previous systematic review that reported on RPM interventions and the impact on acute care use. Included studies were published between 2015-2020.

Primary and secondary outcome measures: Contextual factors and potential mechanisms that led to variation in acute care use (hospitalisations, length of stay, or emergency department presentations).

Results: We found that across a broad range of RPM interventions 31 factors emerged that are likely to impact the effectiveness of RPM innovations on acute care use. These were synthesised into six theories of intervention success: 1) targeting populations at high risk; 2) accurately detecting a decline in health; 3) providing responsive and timely care; 4) personalising care; 5) enhancing self-management and, 6) ensuring collaborative and coordinated care.

Conclusion: While RPM interventions are complex, if they are designed with patients, providers and the implementation setting in mind and with the key variables identified within this review incorporated, it is more likely that they will be effective at reducing acute hospital events.

Registration: The protocol for our review was registered (#CRD42020142523) with the Prospective Register of Systematic Reviews (PROSPERO).

Strengths and limitations

- Our review was strengthened by a comprehensive search and inclusivity of diverse RPM interventions across a broad spectrum of conditions and contexts.
- The novel use of realist review methodology and development of theory-based constructs helped to systematically identify factors impacting upon implementation.
- Included studies within our review had multiple study design issues. Typically, with many of these studies it is not possible (or ethical) to blind participants. Therefore, selection bias may have effected results if health professionals pragmatically selected more willing or engaged patients to participate in the trials.
- While our focus was on acute care use, other aspects of care may have been overlooked that relate to care quality.

Introduction

Non-communicable diseases such as heart disease, chronic obstructive pulmonary disease (COPD), and diabetes accounts for over 70 per cent of global deaths each year.[1] Combined with the added challenge of ageing populations, health systems internationally are under enormous strain to support growing numbers of chronically unwell people.[2] One of the main drivers of healthcare costs for chronically ill patients results from acute hospital admissions due to their intense resource requirements. Consequently, new models of care are being widely investigated and trialled that could extend care into the home and prevent unnecessary acute care events.

Remote patient monitoring (RPM) is a telehealth innovation that offers significant opportunities to increase the timeliness of care, enhance health outcomes, and potentially reduce hospitalisations and associated healthcare costs.[3, 4] RPM uses technology to observe a patient's physiological (e.g. heart rate, blood pressure) and behavioural (e.g. medication adherence, physical activity) information from a distance.[5] With support, many individuals could effectively self-manage chronic conditions in the community.[6] Further, if alerted early, healthcare providers could intervene when a person's health is declining, potentially preventing costly escalations to hospital. Health professionals can routinely monitor a patient's health data and/or be alerted when measurements exceed a pre-determined threshold. This allows for early intervention and ideally prevention of further exacerbation of a condition. RPM can benefit people with chronic illness as well as other population groups that benefit from continuous monitoring such as the frail and elderly, neonates or post-surgical patients.[5]

Despite the potential benefits of RPM, investigations into its clinical and cost effectiveness have provided mixed results to date. For example, the impact of RPM on the heart failure population has resulted in multiple systematic reviews[7], meta-analyses[8, 9], and reviews of reviews.[10, 11] These reviews are generally positive about the potential benefits for patients and health services from RPM services,[7, 8, 10, 12] but others also report limited or no effect[9] on reducing morbidity and mortality. A 2018 Cochrane review reported no difference in all-cause mortality in remotely monitored patients with heart failure and a change in hospitalisations ranging from a 64% decrease to a 60% increase.[9]

In our recent review[13], we provided a synthesis of the available evidence for the effect of RPM on acute care use including hospital admission events, hospital length of stay, and emergency department presentations. We found that RPM was reported to reduce acute care use in approximately 45% of studies. Remaining studies largely reported no change; however, some reported an increase in acute care use. The included 91 studies covered multiple chronic conditions, countries and health care organisations and used various technology and models of care. While RPM can have a positive impact on reducing acute care use, certain enables are needed. Clinicians, researchers, and policymakers require more guidance on how to design and implement RPM-facilitated models of care to achieve the greatest benefit. Consequently, further analysis is required to understand underlying mechanisms causing such variation in acute care use across RPM interventions.

We sought to understand what causes variation in outcomes from RPM interventions. Realist review methodology enables exploration of how, why and for whom interventions do and do not work. Consequently, the approach has been used across various health interventions (e.g. medical education programs [14], school feeding programs[15]). The basic tenant of realist philosophy is that the effectiveness of an intervention is impacted by the context in which it is implemented which will trigger mechanisms that result in intended and unintended outcomes.[16] Realist reviews are particularly helpful for complex interventions like RPM interventions where the effectiveness is

impacted by multiple interacting components such as the intervention design, users, interpersonal relationships and institutions and settings where the intervention is delivered.

Specifically, this study aims to (1) identify factors of RPM interventions that relate to increased and decreased acute care use, and (2) develop recommendations for future RPM intervention design and implementation.

Methods

Data extraction

We used data from our recent systematic review[13] that compared acute care use between individuals who were and were not monitored using RPM. Complete details of the original systematic review have been described elsewhere.[13] In brief, search terms for remote monitoring and acute care utilisation were used across three electronic databases: PubMed (MEDLINE)[1966-2020], EMBASE (OvidSP)[1974-2020], and CINAHL (EBSCOHost)[1982-2020]. The search, conducted in October 2020, included articles published in the last five years (2015-2020). Articles were included if they used RPM to monitor an individual's biometrics (e.g. heart rate, blood pressure) from a distance while they are not in hospital. No restrictions were placed on patient age, or disease conditions however full-text studies had to be available in English.

We then re-reviewed the same 91 articles included in our original RPM systematic review, using realist review methodology to identify factors that determine intervention success and failure in various contexts. This review was guided by the work of Pawson et al (2005)[17] and followed guidelines outlined by the Realist and Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES; Appendix A)[18]. According to the methodology described by Pawson et. al.[17] information was extracted that related to context (settings, populations, intervention delivery); outcomes (positive, negative or null effect on outcome of hospital use), and potential mechanisms or reasons behind the results (e.g. author's interpretation as to why the interventions did or did not work). These data were recorded in an Excel spreadsheet to facilitate a structured analysis. Two researchers (ET, MT) independently extracted these data.

Evidence synthesis

The researchers then collectively examined the articles to detect patterns and developed a compendium of explanatory factors observed in the RPM studies. The researchers compared and discussed their identified factors that led to increased or decreased acute care use being reported in the studies. Findings were then combined into a table showing the number of studies proposing each mechanism and grouped by outcome (e.g. increased or decreased acute care use).

The two researchers then jointly mapped recurrent patterns into explanatory context-mechanism-outcome (CMO) diagrams to illustrate how the different factors interact. Literature was also examined for opposing or conflicting viewpoints. These CMO diagrams were discussed with a third member of the research team (LC) to confirm consistent and logical development. Key findings were synthesised into overarching themes, which are referred to as 'theories' in the realist review approach.[17] Finally, a list of recommendations were developed from the findings and ordered by context to guide future RPM intervention design and implementation.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Results

Ninety-one articles from our previous review were evaluated to determine why RPM increased, decreased, or had no effect on acute care use. Thirty-one factors were identified and mapped onto two outcomes: 1) increased hospital use (21 factors) and 2) reduced hospital use (10 factors) (Figures 1 & 2). Factors were also ordered by the frequency of articles that reported them as possible influences on outcomes (represented by the size of each factor in Figure 1 and 2).

[Insert Figure 1]

Figure 1 *Factors associated with RPM intervention studies that reduced acute care use.*

The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.

CIED: Cardiac implantable electronic devices; Pt: patient; RPM: remote patient monitoring

[Insert Figure 2]

Figure 2 *Factors associated with RPM interventions studies that increased acute care use.*

The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.

RPM: remote patient monitoring; Pt: patient

Theories about how RPM works

It was identified that successful RPM interventions, in this case those interventions that successfully reduced acute care use, were those that: 1) *target populations at high risk;* 2) *accurately detect a decline in health; 3)* were *responsive* and *provided timely care; 4) provided personalised care;* 5) *enhanced self-management* and, 6) *ensured collaborative and coordinated care*. Each of these theories of intervention success are described below.

Target populations at high risk

Appropriate selection of patients for RPM is crucial if a change in acute care use is to be achieved. RPM interventions are likely to have more pronounced effects on acute care use when they are targeted towards populations with a high risk of hospitalisation (e.g. moderate-severe disease severity, multiple comorbidities).[19] Further, it is important for the intervention to be timed with periods of high-risk readmissions (e.g. the first 90 days post an index event). Delaying the delivering of RPM devices to patients may reduce the effect[20] (See Figure 3).

Patients who are more likely to present to hospital multiple times have a greater chance of reducing admissions due to more timely interventions. In practice, however, clinicians may have reservations about remotely assessing their most vulnerable and unwell patients. As described by Geller et al.,[21] *"in clinical practice telemedicine seems to be used mainly in patients with better prognosis, probably due to the belief that those who live longer may receive more (i.e. prolonged) benefit from*

telemonitoring than sicker patients who should be seen in the office more frequently" (pg. 1124). Consequently, clinicians may require additional information on how RPM can be safely delivered in high-risk cohorts.

[Insert Figure 3]

Figure 3. *Proposed context-mechanism-outcome:* ***target population***

Accurately detect a decline in health

RPM needs to accurately predict disease exacerbations by detecting a change in symptoms that relate to health deteriorations. This has been a challenge in certain populations such as COPD and heart failure patients which may have unpredictable disease progression. In the COPD population, multiple studies reported trying to determine the measurement (e.g. spirometry, oximetry, or a combination) which would mark the onset of an exacerbation,[22-25] however, none came to a definitive conclusion.[26] RPM can be used in these population groups to longitudinally track the progression of disease and develop parameters to be tested as predictors for future interventions.[27]

In the heart failure population, physiological signs may not provide adequate warning of decompensation. Readmission in this cohort can be a complex interplay of multiple factors and is often not solely limited to physiological variables.[28] If deterioration occurs too quickly, there is limited opportunity to intervene.[29] Therefore, more investigation is required to try and accurately predict health declines for individual patients and accurately pin-point the best way for RPM to be used to support this patient population.

Implantable devices (e.g. pacemakers) have an additional advantage; continuous monitoring enables undiagnosed co-morbid conditions such as atrial fibrillation to be detected enabling pre-emptive intervention.[30] It can also improve the efficiency of outpatient clinical care by detecting device or lead malfunctions earlier.[31]

Provide timely care via a responsive system

Any benefit from RPM is dependent on patients 1) using the system (e.g. timely data entry) and, 2) providers taking appropriate and equally timely action when out-of-range readings occur.[30] Therefore, RPM systems that use automated data entry wherever possible are preferable as they can reduce errors and delays due to manual entry. As technology improves, smartphone-based programs are likely to replace standard RPM equipment which may result in more consistent, accurate and timely data from patients.[19] For innovations that rely on manual data entry, RPM innovations need to be easy to use (e.g. enables efficient data entry, transportable) and useful for patients to ensure long term use and engagement.[32] Additionally, regular monitoring is required. For example, Srivastava et al.[19] routinely monitored data for abnormalities or lack of responses; if a patient did not submit data for three days, a call was initiated by nursing staff.

On the staff end, RPM alerts need to be actioned with timely and appropriate responses; the speed of decision-making and frequency of monitoring is paramount.[33] A fast response often requires frequent contact with patients and effective bi-directional communication pathways between staff

and patients. For example, Trucco et al.[34] facilitated communication between families and the on-call team via a dedicated phone number or email address. Multiple studies report the importance of dedicated care (e.g. providing an RPM nurse or dedicated case manager) in improving response time.[33, 35-38] This is supported by the literature with findings that patients who received either basic or intensive case management spend less time in hospital than those without.[39] "Fast tracked" access to primary care providers was used in the intervention reported by Pedone et al.[40] when abnormalities were presented, or new symptoms arose. They reported that a new model of care, rather than simply implementing a new technology, was required to obtain sizable benefits in terms of hospitalisation outcomes.[40] Where possible, RPM should be embedded into the system and provide seamless interaction between patients and the healthcare system with minimal encumbrance on both ends.[19] The proposed context-mechanism-outcome diagram is provided in Figure 4.

[Insert Figure 4]

Figure 4. *Proposed context-mechanism-outcome:* ***timely care***

Provide personalised care

Providing a patient-centric and personalised approach was also an important factor in determining the success of an RPM intervention in reducing acute care use.[19] Firstly, the development of the RPM innovation needs to be co-designed with patients and their families to ensure it meets their needs and maximise acceptance and uptake.[41] Training patients on how to use the device will likely also need to be personalised and at times repeated. RPM alerts can also be personalised by using individual data to determine alert thresholds. Koelher et al.[42] recommended defining a risk category for each individual patient based on their positive results (derived from biometric data). One study author requested personalised parameters and treatment guidelines from each patient's treating physician.[43] Determining appropriate parameters for RPM applications (personalised or not) enables the treating team to be alerted to any biometric measurements that fall outside of the personalised parameter ranges. To enable these personalised parameters to be developed physicians need to be engaged in the RPM process for their patient early. The response by the RPM monitoring team also needs to be tailored; considering the person's medical, social and emotional needs.

Enhance self-management

To successfully reduce acute care use, RPM interventions should include support and education to increase self-management skills. Through developing knowledge, skills and positive behaviours (e.g. medication adherence), patients are more likely to be able to effectively manage their condition with the aid of RPM (see Figure 5) .[44] Additionally, increased awareness of signs and symptoms of disease progression that often occurs when patients use RPM can prompt them to contact their healthcare provider for timely management.[44] Providing feedback from RPM data in a way that empowers patients to take control of their own health is important. Koelher et al.[42] reported that this needs to be a comprehensive approach including education and patient involvement when developing management strategies. In some instances, RPM interventions were discontinued once patients were able to correctly correlate their personal symptoms and seek help when required.[43]

Conversely, some RPM interventions that were unsuccessful in reducing hospitalisation events reported patients becoming overly reliant on the RPM team, for instance alerting the team know when an issue arose rather than developing autonomous self-management skills for their condition. Additionally, some known important factors such as medication adherence were not always measured and present a lost opportunity in many RPM innovations. Medication adherence and timely changes to medications are reported to confer substantial benefits for patients.[42]

[Insert Figure 5]

Figure 5. *Proposed context-mechanism-outcome:* ***self-management***

Ensure collaborative and coordinated care

Successful RPM studies demonstrated increased connection and communication between healthcare staff and patients.[31] Multidisciplinary team-based interventions that combine feedback (automated and/or provider-initiated) with other approaches (e.g. coaching, motivational interviews, and shared decision-making) are more likely to result in improvement in adherence.[45] Involvement of primary care is crucial. As high-risk patients are often managed by primary and specialty care, both hospital and primary care settings should be involved in RPM interventions.[46] Involvement of key stakeholders is required to improve continuity of care.[47] Beyond healthcare professionals, the RPM intervention should also aim to include families and carers as key stakeholders in the long-term management of the person's condition. To increase primary carers' acceptance of and adherence to RPM, they must be involved very early on. To institute an initial change of role, staff incentives (e.g. financial payments) may be required.[27] Additionally, nursing staff should be considered as having leading roles in RPM interventions.[48] Further, institutional support is required for these initiatives and reorganisation of care processes should be carefully planned and implemented.[48]

Factors that resulted in increased acute care use

A range of factors were identified as having a negative influence on hospital use (increasing admissions) (Figure 2). Many of the identified factors are the reverse of what has been described above. For example, not targeting populations at high risk, not integrating RPM into the workflow or using systems that have measurement errors. For example, multiple study authors reported slow alert response times (N=6)[32, 49-53] and low patient or clinician adherence (N=11) [19, 20, 28, 32, 45, 54-59] as important factors resulting in no change or an increase in acute care use in the RPM group. There also appears to be a delicate balance between providing a supportive environment that empowers patients to self-manage versus having patients become reliant on the RPM device and/or the monitoring team.

Recommendations for RPM

We synthesised multiple recommendations to assist in the design and implementation of RPM interventions (Figure 6).

When designing RPM devices, it is crucial that the measured biometrics accurately predict disease exacerbations. Alert thresholds need to be carefully determined to ensure they are sensitive to physiological changes without being too high, and where possible tailored to the patient and disease state. Further, the transmission of data needs to be reliable, and if possible, automatic.

It is essential that RPM devices are co-designed with consumers and providers to improve usability and engagement with the RPM system. It is likely that making the device interactive and building in feedback loops between the patient and clinician will enhance engagement. However, if this increases the provider's workload it may discourage provider engagement. Multidisciplinary team interventions that combine feedback with other approaches like patient education, motivational interviewing, coaching or shared decision-making are likely to be more effective long-term.[60]

At the organisation level, having dedicated professionals responsible for monitoring data and communicating with patients and the healthcare team can improve the timeliness and coordination of care. Studies with nursing staff in these leading and case-management roles appeared to be more effective.[48] RPM also needs to be embedded into the health system to provide seamless interaction between patients and the healthcare system. This may require reorganisation of care and additional resources (physical and personnel) to support the intervention.

[Insert Figure 6]

Figure 6*. Recommendations to enhance RPM and reduce acute care use*

Discussion

We found that RPM interventions were successful at reducing acute care use when they incorporated a number of elements including; accurately predicting a decline in health or disease exacerbation, timely response to alerts, personalised patient parameters, and a focus on enhancing patient self-management. Additionally, RPM needed to improve the continuity of care by enhancing collaboration between specialists and primary care. To the best of our knowledge, this is the first review to elucidate why some RPM interventions are more successful than others in reducing acute care use.

RPM interventions are complex because they typically involving multiple components (e.g. data collection, education, feedback) and various stakeholders across different settings (e.g. community, primary and tertiary care). Given the complexity of RPM interventions, it is perhaps unsurprising that RPM studies have resulted in so much variation in the effects demonstrated regarding changes in acute care use. To date, much of the focus of RPM innovations has been on the design and development of the technology.[61, 62] While functioning technology that accurate detects a decline in health is important, to deliver significant benefits RPM alerts must also lead to an actionable and timely responses. To achieve positive results at the healthcare system level, RPM interventions require a change to the *model of care* rather than simple technology implementation.[63]

To be successful, the right patients need to be recruited at the right time. Patients with greater disease severity and at high risk of readmissions appear to confer the greatest benefit of RPM interventions in terms of reduced acute care use.[64] For instance, a recent consensus statement from the Heart Failure Society of America[65] broadly concluded that heart failure RPM had the most impact

when patients were most at risk (e.g., recent hospitalisation, prone to fluid overload, and struggles with medication adherence). Additionally, RPM should target patients who are willing and likely to adhere with RPM regimes.

While our study focuses on acute hospital use, other authors have investigated patient-related factors that may support long-term monitoring of conditions. For example, Huygens suggests there is a relationship between perceived disease controllability and patients' willingness to self-monitor.[66] Patients with diabetes, asthma and hypertension were most willing to self-monitor. In contrast, patients with rheumatism, migraines and other neurological disorders were less willing. The intervention design can facilitate engagement and use. Hong and Lee[64] determined that interventions with an educational component such as self-management programs have greater effects. Another consideration is the patient's social circumstance. One study found that RPM significantly improved outcomes for socially isolated patients,[67] potentially due to the delay in care access that these patients may face. Conversely, for socially connected patients, outcomes appear to be enhanced by training caregivers.[29, 68]

Interventions based on health behaviour models and personalised coaching were most successful.[69] The findings of this review parallel some of the themes in a review of patient experiences of RPM by Walker et al.[70] Similarly, self-management and early identification of clinical exacerbations were key to preventing hospitalisation. From the patient perspective, self-management was achieved by increasing confidence and providing a sense of safety. Shared decision making was identified as a key mechanism to preventing hospitalisation. Conversely, interventions that provided information but did not equip patients to self-manage were potentially at greater risk of having patients become overly reliant on the RPM team.

Patients have previously reported concerns about being lost in the data or losing interpersonal connections with health professionals and a reluctance to try something new, especially if unfamiliar with technology.[70] Our findings substantiate the importance of co-designing RPM interventions with consumers to ensure they are easy to use and provide useful feedback to maintain adherence and engagement. Building rapport, providing training (sometimes multiple times) and having a two-way interactive relationship between the patient and the RPM team is crucial. Alternatively, a lack of education and timely response were identified as factors that increased acute care use.

Included studies within our review had multiple study design issues. Typically, with many of these studies it is not possible (or ethical) to blind participants. Therefore, selection bias may have effected results if health professionals pragmatically selected more willing or engaged patients to participate in the trials. However, in real-world clinical settings it is likely (and appropriate) that participants are provided with options regarding their follow-up care. The observer or Hawthorne effect[71] may be at play with participants potentially acting differently due to a belief that they are being watched. Such an effect may reduce with time, and some trial lengths may have been too short for this effect to wear off. Potentially the higher number of studies reporting positive outcomes may be due to a reporting bias within the literature; consequently, there were a higher number of factors discussed in relation to reducing (n=21) rather than increasing acute care use (n=10).

Our review was strengthened by a comprehensive search and inclusivity of diverse RPM interventions across a broad spectrum of conditions and contexts. The novel use of realist review methodology and development of theory-based constructs helped to systematically identify factors impacting upon implementation. However, while our focus was on acute care use, other aspects of care may have been overlooked that relate to care quality. Further, it is possible that reducing hospital admissions may shift care and associated costs to the primary care setting and potentially result in additional pressure and stress on different aspects of the system. Additionally, the theories

that have been developed are based on both our and the primary study authors' interpretation of findings in many instances and not experimental evidence.

Conclusion

RPM interventions have the potential to reduce acute care use when they are targeted to appropriate populations and disease states, designed well, and implemented with patients and providers in mind. This review has highlighted important considerations for developing effective RPM devices, systems and telehealth models of care. To achieve significant changes in acute care use, RPM data needs to be routinely entered and checked, automated where possible, alerts need to accurately highlight when a person's data is beyond an acceptable range (for that person), and healthcare staff need to respond in a timely and appropriate manner. Further, information and feedback needs be provided to patients in a way that empowers them to self-manage their condition. If designed with these considerations in mind, RPM interventions are more likely to be effective at reduce acute care use. Future studies should investigate any unintended consequences of RPM and cost implications resulting from the shifting of care.

List of abbreviations

COPD: chronic obstructive pulmonary disease; CMO: context-mechanism-outcome; PROSPERO: Prospective Register of Systematic Reviews; RAMESES: Realist and Meta-narrative Evidence Synthesis: Evolving Standards; RPM: Remote patient monitoring.

Declarations

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Consent for publication: All authors consent to publication

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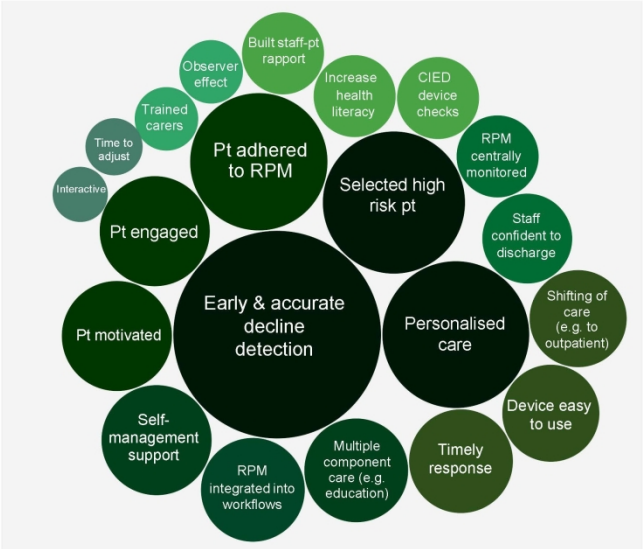

Figure 1 Factors associated with RPM intervention studies that reduced acute care use.
The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.
CIED: Cardiac implantable electronic devices; Pt: patient; RPM: remote patient monitoring

364x215mm (192 x 192 DPI)

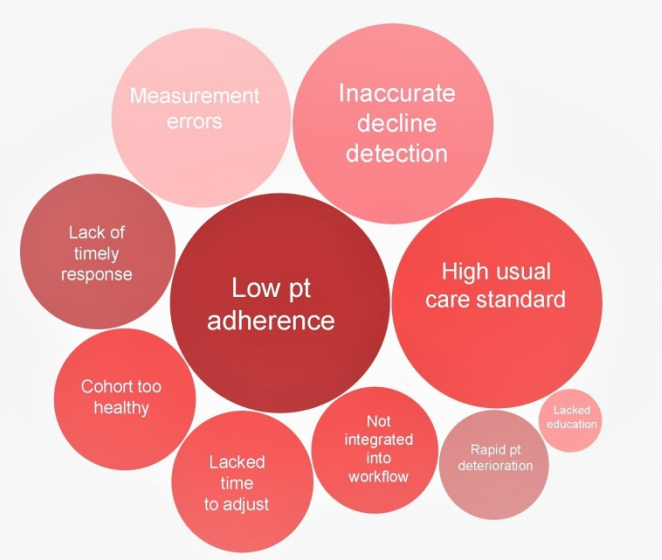

Figure 2 Factors associated with RPM interventions studies that increased acute care use.
The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.
RPM: remote patient monitoring; Pt: patient

728x431mm (96 x 96 DPI)

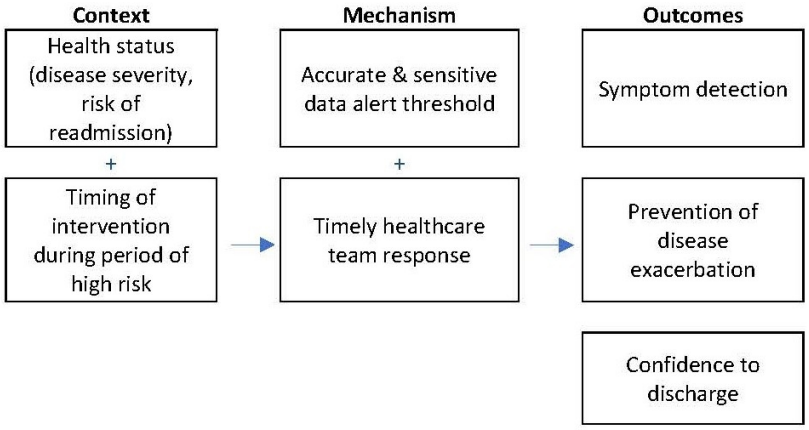

Figure 3. Proposed context-mechanism-outcome: target population

310x171mm (96 x 96 DPI)

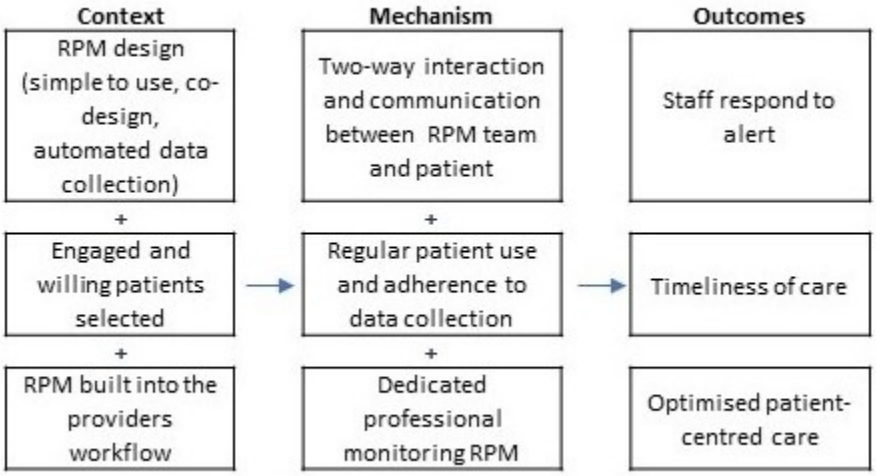

Figure 4. Proposed context-mechanism-outcome: timely care

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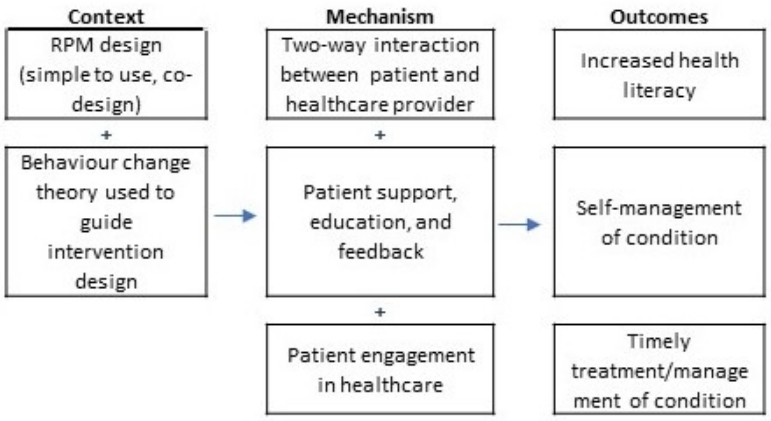

Figure 5. Proposed context-mechanism-outcome: self-management

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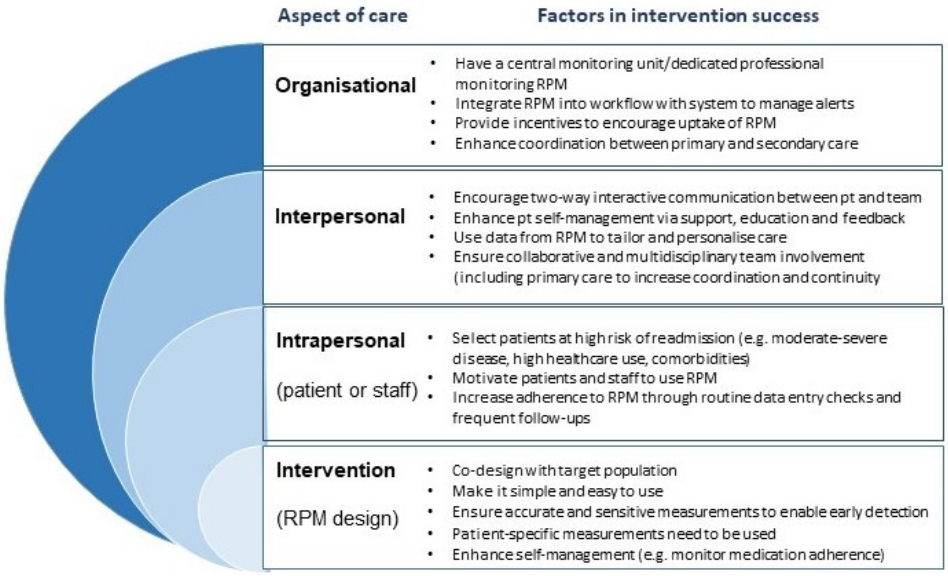

Figure 6. Recommendations to enhance RPM and reduce acute care use

192x128mm (96 x 96 DPI)

Appendix A

RAMESES publication standards: realist synthesis

Wong, G., Greenhalgh, T., Westhorp, G. *et al.* RAMESES publication standards: realist syntheses. *BMC Med* **11,** 21 (2013). https://doi.org/10.1186/1741-7015-11-21

TITLE			**Pg No.**
1		In the title, identify the document as a realist synthesis or review	1
ABSTRACT			
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	2
INTRODUCTION			
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	3
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	3
METHODS			
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.	N/A

TITLE			Pg No.
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.	4
7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.	4
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	4
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these.	4. also additional details provided in previously published paper
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.	As above
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.	As above
RESULTS			
12	Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider	This paper included articles from a previously published review that followed the PRISMA guidelines – the flow

TITLE			Pg No.
		using the example templates (which are likely to need modification to suit the data) that are provided.	diagram is published within that paper.
13	Document characteristics	Provide information on the characteristics of the documents included in the review.	4-8
14	Main findings	Present the key findings with a specific focus on theory building and testing.	4-8
DISCUSSION			
15	Summary of findings	Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).	9
16	Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.	10
17	Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.	9-10
18	Conclusion and recommendations	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	10/11
19	Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers.	1

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Factors influencing effectiveness of remote patient monitoring interventions: A realist review

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Factors influencing effectiveness of remote patient monitoring interventions: A realist review

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Key words: telehealth; telemedicine; telecare; remote monitoring; telemonitoring; in-home monitoring; hospitalization; length of stay; realist review

Abstract (300 words)

Objectives: Our recent systematic review determined that remote patient monitoring (RPM) interventions can reduce acute care use. However, effectiveness varied within and between populations. Clinicians, researchers, and policymakers require more than evidence of effect; they need guidance on how best to design and implement RPM interventions. Therefore, this study aimed to explore these results further to (1) identify factors of RPM interventions that relate to increased and decreased acute care use, and (2) develop recommendations for future RPM interventions.

Design: Realist review - a qualitative systematic review method which aims to identify and explain why intervention results vary in different situations. We analysed secondarily ninety-one studies included in our previous systematic review that reported on RPM interventions and the impact on acute care use. Online databases PubMed, EMBASE and CINAHL were searched in October 2020. Included studies were published in English during 2015-2020 and used RPM to monitor an individual's biometric data (e.g. heart rate, blood pressure) from a distance.

Primary and secondary outcome measures: Contextual factors and potential mechanisms that led to variation in acute care use (hospitalisations, length of stay, or emergency department presentations).

Results: Across a range of RPM interventions 31 factors emerged that impact the effectiveness of RPM innovations on acute care use. These were synthesised into six theories of intervention success: 1) targeting populations at high risk; 2) accurately detecting a decline in health; 3) providing responsive and timely care; 4) personalising care; 5) enhancing self-management and, 6) ensuring collaborative and coordinated care.

Conclusion: While RPM interventions are complex, if they are designed with patients, providers and the implementation setting in mind and incorporate the key variables identified within this review , it is more likely that they will be effective at reducing acute hospital events.

Registration: The review protocol was registered with PROSPERO (#CRD42020142523).

Strengths and limitations

- Our review was strengthened by a comprehensive search and inclusivity of diverse RPM interventions across a broad spectrum of conditions and contexts.
- The novel use of realist review methodology and development of theory-based constructs helped to systematically identify factors impacting implementation.
- Included studies within our review had multiple study design issues. Typically, with many of these studies it is not possible (or ethical) to blind participants. Therefore, selection bias may have affected results if health professionals pragmatically selected more willing or engaged patients to participate in the trials.
- While our focus was on acute care use, other aspects of care may have been overlooked that relate to care quality.

Introduction

Non-communicable diseases such as heart disease, chronic obstructive pulmonary disease (COPD), and diabetes accounts for over 70 per cent of global deaths each year.[1] Combined with the added challenge of ageing populations, health systems internationally are under enormous strain to support growing numbers of chronically unwell people.[2] One of the main drivers of healthcare costs for chronically ill patients results from acute hospital admissions due to their intense resource requirements. Consequently, new models of care are being widely investigated and trialled that could extend care into the home and prevent unnecessary acute care events.

Remote patient monitoring (RPM) is a telehealth innovation that offers significant opportunities to increase the timeliness of care, enhance health outcomes, and potentially reduce hospitalisations and associated healthcare costs.[3, 4] RPM uses technology to observe a patient's physiological (e.g. heart rate, blood pressure) and behavioural (e.g. medication adherence, physical activity) information from a distance.[5] With support, many individuals could effectively self-manage chronic conditions in the community.[6] Further, if alerted early, healthcare providers could intervene when a person's health is declining, potentially preventing costly escalations to hospital. Health professionals can routinely monitor a patient's health data and/or be alerted when measurements exceed a pre-determined threshold. This allows for early intervention and ideally prevention of further exacerbation of a condition. RPM can benefit people with chronic illness as well as other population groups that benefit from continuous monitoring such as the frail and elderly, neonates or post-surgical patients.[5]

Despite the potential benefits of RPM, investigations into its clinical and cost effectiveness have provided mixed results to date. For example, the impact of RPM on the heart failure population has resulted in multiple systematic reviews[7], meta-analyses[8, 9], and reviews of reviews.[10, 11] These reviews are generally positive about the potential benefits for patients and health services from RPM services,[7, 8, 10, 12] but others also report limited or no affect[9] on reducing morbidity and mortality. A 2018 Cochrane review reported no difference in all-cause mortality in remotely monitored patients with heart failure and a change in hospitalisations ranging from a 64% decrease to a 60% increase.[9]

In our recent review[13], we provided a synthesis of the available evidence for the effect of RPM on acute care use including hospital admission events, hospital length of stay, and emergency department presentations. We found that RPM was reported to reduce acute care use in approximately 45% of studies. Remaining studies largely reported no change; however, some reported an increase in acute care use. The included 91 studies covered multiple chronic conditions, countries and health care organisations and used various technology and models of care. While RPM can have a positive impact on reducing acute care use, certain enablers are needed. Clinicians, researchers, and policymakers require more guidance on how to design and implement RPM-facilitated models of care to achieve the greatest benefit. Consequently, further analysis is required to understand underlying mechanisms causing such variation in acute care use across RPM interventions.

We sought to understand what causes variation in outcomes from RPM interventions. Realist review methodology enables exploration of how, why and for whom interventions do and do not work. Consequently, the approach has been used across various health interventions (e.g. medical education programs [14], school feeding programs[15]). The basic tenet of realist philosophy is that the effectiveness of an intervention is impacted by the context in which it is implemented which may trigger mechanisms that result in intended and unintended outcomes.[16] Realist reviews are particularly helpful for complex interventions like RPM interventions where the effectiveness is

impacted by multiple interacting components such as the intervention design, users, interpersonal relationships and institutions and settings where the intervention is delivered.

Specifically, this study aimed to (1) identify factors of RPM interventions that relate to increased and decreased acute care use, and (2) develop recommendations for future RPM intervention design and implementation.

Methods

Data extraction

We used data from our recent systematic review[13] that compared acute care use between individuals who were and were not monitored using RPM. Complete details of the original systematic review have been described elsewhere.[13] In brief, search terms for remote monitoring and acute care utilisation were used across three electronic databases: PubMed (MEDLINE)[1966-2020], EMBASE (OvidSP)[1974-2020], and CINAHL (EBSCOHost)[1982-2020]. The search, conducted in October 2020, included articles published in the last five years (2015-2020). Articles were included if they used RPM to monitor an individual's biometrics (e.g. heart rate, blood pressure) from a distance while they are not in hospital. No restrictions were placed on patient age, or disease conditions however full-text studies had to be available in English.

We then re-reviewed the same 91 articles included in our original RPM systematic review, using realist review methodology to identify factors that determine intervention success and failure in various contexts. This review was guided by the work of Pawson et al. (2005)[17] and followed guidelines outlined by the Realist and Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES; Appendix A)[18]. Following the methodology described by Pawson et. al.,[17] information was extracted that related to context (settings, populations, intervention delivery), outcomes (positive, negative or null affect on outcome of hospital use), and potential mechanisms or reasons behind the results (e.g. author's interpretation as to why the interventions did or did not work). These data were recorded in an Excel spreadsheet to facilitate a structured analysis. Two researchers (ET, MT) independently extracted these data.

Evidence synthesis

The researchers then collectively examined the articles to detect patterns and developed a compendium of explanatory factors observed in the RPM studies. The researchers compared and discussed their identified factors that led to increased or decreased acute care use being reported in the studies. Findings were then combined into a table showing the number of studies proposing each mechanism and grouped by outcome (e.g. increased or decreased acute care use).

The two researchers then jointly mapped recurrent patterns into explanatory context-mechanism-outcome (CMO) diagrams to illustrate how the different factors interact. Literature was also examined for opposing or conflicting viewpoints. These CMO diagrams were discussed with a third member of the research team (LC) to confirm consistent and logical development. Key findings were synthesised into overarching themes, which are referred to as 'theories' in the realist review approach.[17] Finally, a list of recommendations were developed from the findings and ordered by context to guide future RPM intervention design and implementation.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Results

Ninety-one articles from our previous review were evaluated to determine why RPM increased, decreased, or had no affect on acute care use. Thirty-one factors were identified and mapped onto two outcomes: 1) increased hospital use (21 factors) and 2) reduced hospital use (10 factors) (Figures 1 & 2). Factors were also ordered by the frequency of articles that reported them as possible influences on outcomes (represented by the size of each factor in Figure 1 and 2).

[Insert Figure 1]

Figure 1 *Factors associated with RPM intervention studies that reduced acute care use.*

The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.

CIED: Cardiac implantable electronic devices; Pt: patient; RPM: remote patient monitoring

[Insert Figure 2]

Figure 2 *Factors associated with RPM interventions studies that increased acute care use.*

The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.

RPM: remote patient monitoring; Pt: patient

Theories about how RPM works

It was identified that successful RPM interventions, in this case those interventions that successfully reduced acute care use, were those that: 1) *target populations at high risk;* 2) *accurately detect a decline in health; 3)* were *responsive* and *provided timely care; 4) provided personalised care;* 5) *enhanced self-management* and, 6) *ensured collaborative and coordinated care*. Each of these theories of intervention success are described below.

Target populations at high risk

Appropriate selection of patients for RPM is crucial if a change in acute care use is to be achieved. RPM interventions are likely to have more pronounced effects on acute care use when they are targeted towards populations with a high risk of hospitalisation (e.g. moderate-severe disease severity, multiple comorbidities).[19] Further, it is important for the intervention to be timed with periods of high-risk readmissions (e.g. the first 90 days post an index event). Delaying the delivering of RPM devices to patients may reduce the effect[20] (See Figure 3).

Patients who are more likely to present to hospital multiple times have a greater chance of reducing admissions due to more timely interventions. In practice, however, clinicians may have reservations about remotely assessing their most vulnerable and unwell patients. As described by Geller et al.,[21] *"in clinical practice telemedicine seems to be used mainly in patients with better prognosis, probably due to the belief that those who live longer may receive more (i.e. prolonged) benefit from*

telemonitoring than sicker patients who should be seen in the office more frequently" (pg. 1124). Consequently, clinicians may require additional information on how RPM can be safely delivered in high-risk cohorts.

[Insert Figure 3]

Figure 3. *Proposed context-mechanism-outcome:* ***target population***

Accurately detect a decline in health

RPM needs to accurately predict disease exacerbations by detecting a change in symptoms that relate to health deteriorations. This has been a challenge in certain populations such as COPD and heart failure patients which may have unpredictable disease progression. In the COPD population, multiple studies reported trying to determine the measurement (e.g. spirometry, oximetry, or a combination) which would mark the onset of an exacerbation,[22-25] however, none came to a definitive conclusion.[26] RPM can be used in these population groups to longitudinally track the progression of disease and develop parameters to be tested as predictors for future interventions.[27]

In the heart failure population, physiological signs may not provide adequate warning of decompensation. Readmission in this cohort can be a complex interplay of multiple factors and is often not solely limited to physiological variables.[28] If deterioration occurs too quickly, there is limited opportunity to intervene.[29] Therefore, more investigation is required to try and accurately predict health declines for individual patients and accurately pin-point the best way for RPM to be used to support this patient population.

Implantable devices (e.g. pacemakers) have an additional advantage; continuous monitoring enables undiagnosed co-morbid conditions such as atrial fibrillation to be detected enabling pre-emptive intervention.[30] It can also improve the efficiency of outpatient clinical care by detecting device or lead malfunctions earlier.[31]

Provide timely care via a responsive system

Any benefit from RPM is dependent on patients 1) using the system (e.g. timely data entry) and, 2) providers taking appropriate and equally timely action when out-of-range readings occur.[30] Therefore, RPM systems that use automated data entry wherever possible are preferable as they can reduce errors and delays due to manual entry. As technology improves, smartphone-based programs are likely to replace standard RPM equipment which may result in more consistent, accurate and timely data from patients.[19] For innovations that rely on manual data entry, RPM innovations need to be easy to use (e.g. enable efficient data entry, transportable) and useful for patients to ensure long term use and engagement.[32] Additionally, regular monitoring is required. For example, Srivastava et al.[19] routinely monitored data for abnormalities or lack of responses; if a patient did not submit data for three days, a call was initiated by nursing staff.

On the staff end, RPM alerts need to be actioned with timely and appropriate responses; the speed of decision-making and frequency of monitoring is paramount.[33] A fast response often requires frequent contact with patients and effective bi-directional communication pathways between staff

and patients. For example, Trucco et al.[34] facilitated communication between families and the on-call team via a dedicated phone number or email address. Multiple studies report the importance of dedicated care (e.g. providing an RPM nurse or dedicated case manager) in improving response time.[33, 35-38] This is supported by the literature with findings that patients who received either basic or intensive case management spend less time in hospital than those without.[39] "Fast tracked" access to primary care providers was used in the intervention reported by Pedone et al.[40] when abnormalities were presented, or new symptoms arose. They reported that a new model of care, rather than simply implementing a new technology, was required to obtain sizable benefits in terms of hospitalisation outcomes.[40] Where possible, RPM should be embedded into the system and provide seamless interaction between patients and the healthcare system with minimal encumbrance on both ends.[19] The proposed context-mechanism-outcome diagram is provided in Figure 4.

[Insert Figure 4]

Figure 4. *Proposed context-mechanism-outcome:* ***timely care***

Provide personalised care

Providing a patient-centric and personalised approach was also an important factor in determining the success of an RPM intervention in reducing acute care use.[19] Firstly, the development of the RPM innovation needs to be co-designed with patients and their families to ensure it meets their needs and maximises acceptance and uptake.[41] Training patients on how to use the device will likely also need to be personalised and at times repeated. RPM alerts can also be personalised by using individual data to determine alert thresholds. Koelher et al.[42] recommended defining a risk category for each individual patient based on their positive results (derived from biometric data). One study author requested personalised parameters and treatment guidelines from each patient's treating physician.[43] Determining appropriate parameters for RPM applications (personalised or not) enables the treating team to be alerted to any biometric measurements that fall outside of the parameter ranges. To enable personalised parameters to be developed, physicians need to be engaged in the RPM process for their patient early. The response by the RPM monitoring team also needs to be tailored; considering the person's medical, social and emotional needs.

Enhance self-management

To successfully reduce acute care use, RPM interventions should include support and education to increase self-management skills. Through developing knowledge, skills and positive behaviours (e.g. medication adherence), patients are more likely to be able to effectively manage their condition with the aid of RPM (see Figure 5) .[44] Additionally, increased awareness of signs and symptoms of disease progression that often occurs when patients use RPM can prompt them to contact their healthcare provider for timely management.[44] Providing feedback from RPM data in a way that empowers patients to take control of their own health is important. Koelher et al.[42] reported that this needs to be a comprehensive approach including education and patient involvement when developing management strategies. In some instances, RPM interventions were discontinued once patients were able to correctly correlate their personal symptoms and seek help when required.[43]

Conversely, some RPM interventions that were unsuccessful in reducing hospitalisation events reported patients becoming overly reliant on the RPM team, for instance, alerting the team when an issue arose rather than developing autonomous self-management skills for their condition. Additionally, some known important factors such as medication adherence were not always measured and present a lost opportunity in many RPM innovations. Medication adherence and timely changes to medications are reported to confer substantial benefits for patients.[42]

[Insert Figure 5]

Figure 5. *Proposed context-mechanism-outcome:* ***self-management***

Ensure collaborative and coordinated care

Successful RPM studies demonstrated increased connection and communication between healthcare staff and patients.[31] Multidisciplinary team-based interventions that combine feedback (automated and/or provider-initiated) with other approaches (e.g. coaching, motivational interviews, and shared decision-making) are more likely to result in improvement in adherence.[45] Involvement of primary care is crucial. As high-risk patients are often managed by primary and specialty care, both hospital and primary care settings should be involved in RPM interventions.[46] Involvement of key stakeholders is required to improve continuity of care.[47] Beyond healthcare professionals, the RPM intervention should also aim to include families and carers as key stakeholders in the long-term management of the person's condition. To increase primary carers' acceptance of and adherence to RPM, they must be involved very early on. To institute an initial change of role, staff incentives (e.g. financial payments) may be required.[27] Additionally, nursing staff should be considered as having leading roles in RPM interventions.[48] Further, institutional support is required for these initiatives and reorganisation of care processes should be carefully planned and implemented.[48]

Factors that resulted in increased acute care use

A range of factors were identified as having a negative influence on hospital use (increasing admissions) (Figure 2). Many of the identified factors are the reverse of what has been described above. For example, not targeting populations at high risk, not integrating RPM into the workflow, or using systems that have measurement errors. For example, multiple study authors reported slow alert response times (N=6)[32, 49-53] and low patient or clinician adherence (N=11) [19, 20, 28, 32, 45, 54-59] as important factors resulting in no change or an increase in acute care use in the RPM group. There also appears to be a delicate balance between providing a supportive environment that empowers patients to self-manage versus having patients become reliant on the RPM device and/or the monitoring team.

Recommendations for RPM

We synthesised multiple recommendations to assist in the design and implementation of RPM interventions (Figure 6).

When designing RPM devices, it is crucial that the measured biometrics accurately predict disease exacerbations. Alert thresholds need to be carefully determined to ensure they are sensitive to physiological changes without being too high, and where possible tailored to the patient and disease state. Further, the transmission of data needs to be reliable, and if possible, automatic.

It is essential that RPM devices are co-designed with consumers and providers to improve usability and engagement with the RPM system. It is likely that making the device interactive and building in feedback loops between the patient and clinician will enhance engagement. However, if this increases the provider's workload it may discourage provider engagement. Multidisciplinary team interventions that combine feedback with other approaches like patient education, motivational interviewing, coaching or shared decision-making are likely to be more effective long-term.[60]

At the organisation level, having dedicated professionals responsible for monitoring data and communicating with patients and the healthcare team can improve the timeliness and coordination of care. Studies with nursing staff in these leading and case-management roles appeared to be more effective.[48] RPM also needs to be embedded into the health system to provide seamless interaction between patients and the healthcare system. This may require reorganisation of care and additional resources (physical and personnel) to support the intervention.

[Insert Figure 6]

Figure 6*. Recommendations to enhance RPM and reduce acute care use*

Discussion

We found that RPM interventions were successful at reducing acute care use when they incorporated a number of elements including: accurately predicting a decline in health or disease exacerbation, timely response to alerts, personalised patient parameters, and a focus on enhancing patient self-management. Additionally, collaboration between specialists and primary care provides was required to improve the continuity of care To the best of our knowledge, this is the first review to elucidate why some RPM interventions are more successful than others in reducing acute care use.

RPM interventions are complex because they typically involving multiple components (e.g. data collection, education, feedback) and various stakeholders across different settings (e.g. community, primary and tertiary care). Given the complexity of RPM interventions, it is perhaps unsurprising that RPM studies have resulted in so much variation in the effects demonstrated regarding changes in acute care use. To date, much of the focus of RPM innovations has been on the design and development of the technology.[61, 62] While functioning technology that accurate detects a decline in health is important, to deliver significant benefits RPM alerts must also lead to an actionable and timely responses. To achieve positive results at the healthcare system level, RPM interventions require a change to the *model of care* rather than simple technology implementation.[63]

To be successful, the right patients need to be recruited at the right time. Patients with greater disease severity and at high risk of readmissions appear to confer the greatest benefit of RPM interventions in terms of reduced acute care use.[64] For instance, a recent consensus statement from the Heart Failure Society of America[65] broadly concluded that heart failure RPM had the most impact

when patients were most at risk (e.g., recent hospitalisation, prone to fluid overload, and struggles with medication adherence). Additionally, RPM should target patients who are willing and likely to adhere with RPM regimes.

While our study focuses on acute hospital use, other authors have investigated patient-related factors that may support long-term monitoring of conditions. For example, Huygens suggests there is a relationship between perceived disease controllability and patients' willingness to self-monitor.[66] Patients with diabetes, asthma and hypertension were most willing to self-monitor. In contrast, patients with rheumatism, migraines and other neurological disorders were less willing. The intervention design can facilitate engagement and use. Hong and Lee[64] determined that interventions with an educational component such as self-management programs have greater effects. Another consideration is the patient's social circumstance. One study found that RPM significantly improved outcomes for socially isolated patients,[67] potentially due to the delay in care access that these patients may face. Conversely, for socially connected patients, outcomes appear to be enhanced by training caregivers.[29, 68]

Interventions based on health behaviour models and personalised coaching were most successful.[69] The findings of this review parallel some of the themes in a review of patient experiences of RPM by Walker et al.[70] Similarly, self-management and early identification of clinical exacerbations were key to preventing hospitalisation. From the patient perspective, self-management was achieved by increasing confidence and providing a sense of safety. Shared decision making was identified as a key mechanism to preventing hospitalisation. Conversely, interventions that provided information but did not equip patients to self-manage were potentially at greater risk of having patients become overly reliant on the RPM team.

Patients have previously reported concerns about being lost in the data or losing interpersonal connections with health professionals and a reluctance to try something new, especially if unfamiliar with technology.[70] Our findings substantiate the importance of co-designing RPM interventions with consumers to ensure they are easy to use and provide useful feedback to maintain adherence and engagement. Building rapport, providing training (sometimes multiple times) and having a two-way interactive relationship between the patient and the RPM team is crucial. Alternatively, a lack of education and timely response were identified as factors that increased acute care use.

Included studies within our review had multiple study design issues. Typically, with many of these studies it is not possible (or ethical) to blind participants. Therefore, selection bias may have affected results if health professionals pragmatically selected more willing or engaged patients to participate in the trials. However, in real-world clinical settings it is likely (and appropriate) that participants are provided with options regarding their follow-up care. The observer or Hawthorne effect[71] may be at play with participants potentially acting differently due to a belief that they are being watched. Such an effect may reduce with time, and some trial lengths may have been too short for this effect to wear off. Potentially the higher number of studies reporting positive outcomes may be due to a reporting bias within the literature; consequently, there were a higher number of factors discussed in relation to reducing (n=21) rather than increasing acute care use (n=10).

Our review was strengthened by a comprehensive search and inclusivity of diverse RPM interventions across a broad spectrum of conditions and contexts. The novel use of realist review methodology and development of theory-based constructs helped to systematically identify factors impacting upon implementation. However, while our focus was on acute care use, other aspects of care may have been overlooked that relate to care quality. Further, it is possible that reducing hospital admissions may shift care and associated costs to the primary care setting and potentially result in additional pressure and stress on different aspects of the system. Additionally, the theories

that have been developed are based on both our and the primary study authors' interpretation of findings in many instances and not experimental evidence.

Conclusion

RPM interventions have the potential to reduce acute care use when they are targeted to appropriate populations and disease states, designed well, and implemented with patients and providers in mind. This review has highlighted important considerations for developing effective RPM devices, systems, and telehealth models of care. To achieve significant changes in acute care use, RPM data needs to be routinely entered and checked, automated where possible, alerts need to accurately highlight when a person's data is beyond an acceptable range (for that person), and healthcare staff need to respond in a timely and appropriate manner. Further, information and feedback needs be provided to patients in a way that empowers them to self-manage their condition. If designed with these considerations in mind, RPM interventions are more likely to be effective at reducing acute care use. Future studies should investigate any unintended consequences of RPM and cost implications resulting from the shifting of care.

List of abbreviations

COPD: chronic obstructive pulmonary disease; CMO: context-mechanism-outcome; PROSPERO: Prospective Register of Systematic Reviews; RAMESES: Realist and Meta-narrative Evidence Synthesis: Evolving Standards; RPM: Remote patient monitoring.

Declarations

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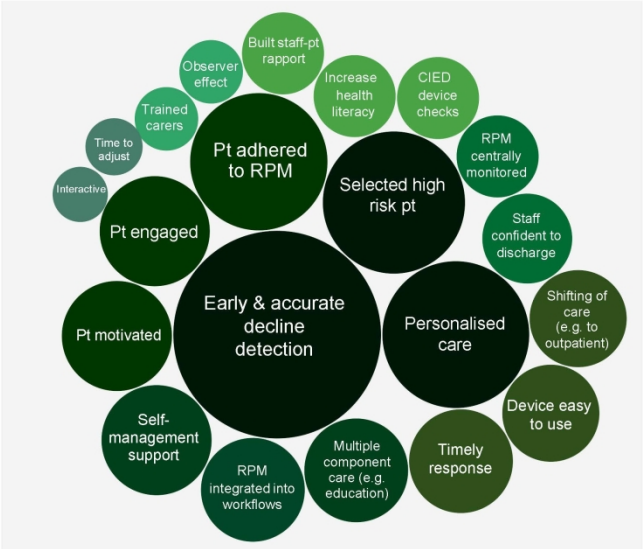

Figure 1 Factors associated with RPM intervention studies that reduced acute care use.
The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.
CIED: Cardiac implantable electronic devices; Pt: patient; RPM: remote patient monitoring

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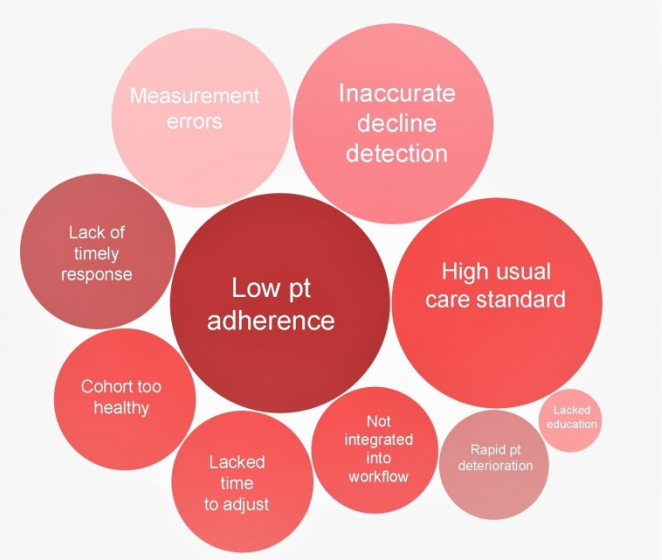

Figure 2 Factors associated with RPM interventions studies that increased acute care use.
The size of each box relates to the number of studies that identified each factor as having an important influence on the outcome.
RPM: remote patient monitoring; Pt: patient

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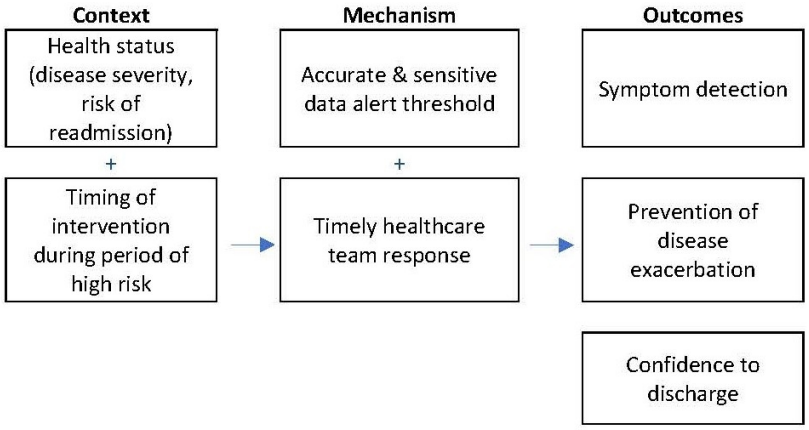

Figure 3. Proposed context-mechanism-outcome: target population

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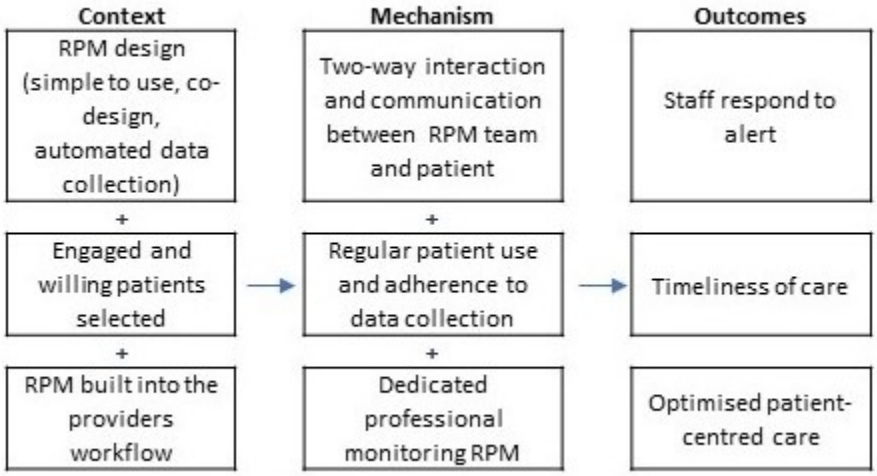

Figure 4. Proposed context-mechanism-outcome: timely care

121x72mm (96 x 96 DPI)

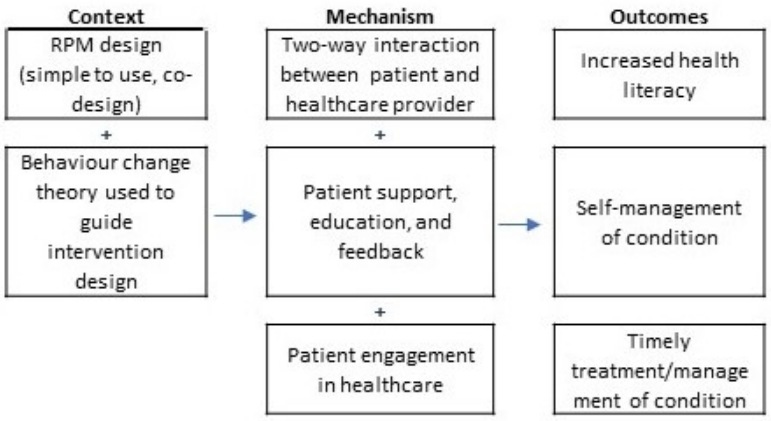

Figure 5. Proposed context-mechanism-outcome: self-management

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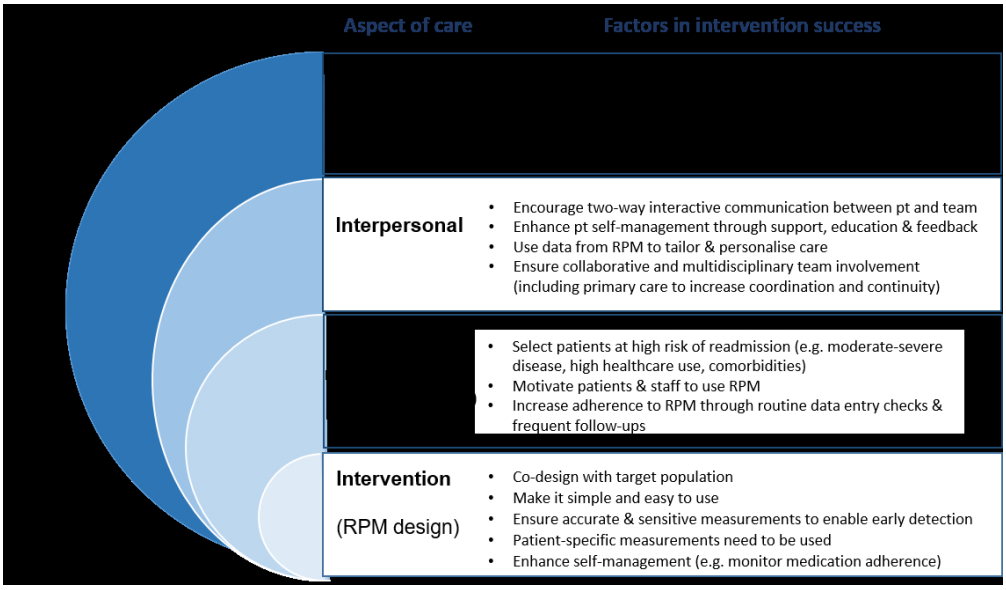
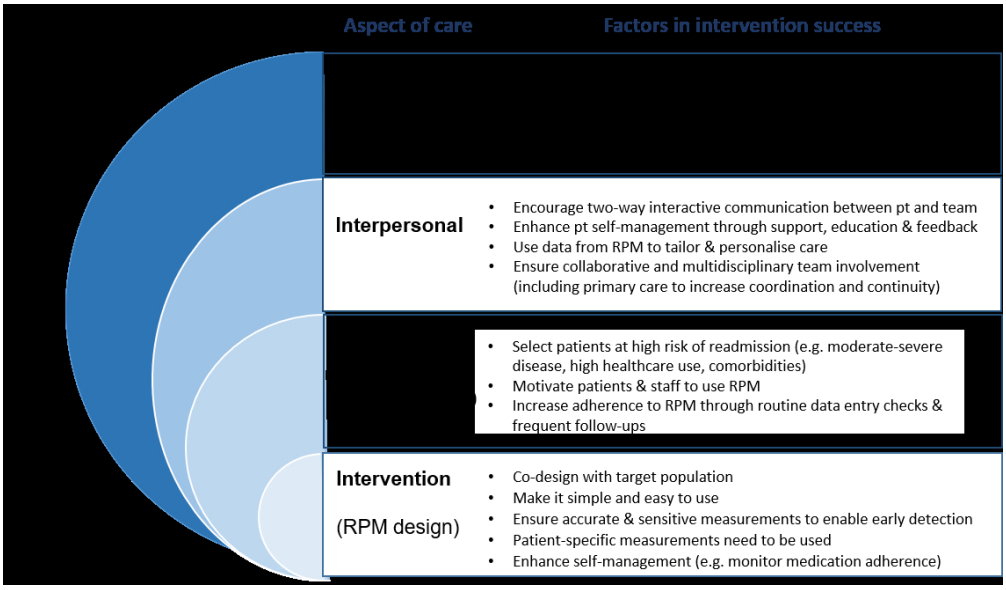


Figure 6: Recommendations to enhance RPM and reduce acute care use

489x284mm (59 x 59 DPI)



489x284mm (59 x 59 DPI)

Appendix A

RAMESES publication standards: realist synthesis

Wong, G., Greenhalgh, T., Westhorp, G. *et al.* RAMESES publication standards: realist syntheses. *BMC Med* **11,** 21 (2013). https://doi.org/10.1186/1741-7015-11-21

TITLE			**Pg No.**
1		In the title, identify the document as a realist synthesis or review	1
ABSTRACT			
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	2
INTRODUCTION			
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	3
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	3
METHODS			
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.	N/A

TITLE			Pg No.
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.	4
7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.	4
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	4
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these.	4. also additional details provided in previously published paper
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.	As above
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.	As above
RESULTS			
12	Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider	This paper included articles from a previously published review that followed the PRISMA guidelines – the flow

TITLE			Pg No.
		using the example templates (which are likely to need modification to suit the data) that are provided.	diagram is published within that paper.
13	Document characteristics	Provide information on the characteristics of the documents included in the review.	4-8
14	Main findings	Present the key findings with a specific focus on theory building and testing.	4-8
DISCUSSION			
15	Summary of findings	Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).	9
16	Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.	10
17	Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.	9-10
18	Conclusion and recommendations	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	10/11
19	Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers.	1