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Around the EQUATOR With Clin-STAR: AI-Based Randomized Controlled Trial Challenges and Opportunities in Aging Research

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ABSTRACT

The CONSORT 2010 statement is a guideline that provides an evidence-based checklist of minimum reporting standards for randomized trials. With the rapid growth of Artificial Intelligence (AI) based interventions in the past 10 years, the CONSORT-AI extension was created in 2020 to provide guidelines for AI-based randomized controlled trials (RCT). The Clin-STAR "Around the EQUATOR" series features existing reported standards while also highlighting the inherent complexities of research involving research of older participants. In this work, we propose that when designing AI-based RCTs involving older adults, researchers adopt a conceptual framework (CONSORT-AI-5Ms) designed around the 5Ms (Mind, Mobility, Medications, Matters most, and Multi-complexity) of Age-Friendly Healthcare Systems. Employing the 5Ms in this context, we provide a detailed rationale and include specific examples of challenges and potential solutions to maximize the impact and value of AI RCTs in an older adult population. By combining the original intent of CONSORT-AI with the 5Ms framework, CONSORT-AI-5Ms provides a patient-centered and equitable perspective to consider when designing AI-based RCTs to address the diverse needs and challenges associated with geriatric care.

1 | Introduction

Artificial Intelligence (AI) refers to systems using data and computing power to simulate human reasoning, process large amounts of data, recognize patterns, make recommendations, and perform many different tasks. With the expansion of AI applications in multiple healthcare domains from triage [1] to quality improvement [2] and clinical decision support [3, 4], there is a growing need for transparency and comprehensiveness in AI reporting standards. Accordingly, there have been efforts to clarify specific guidelines for AI-based research studies to improve transparency and incorporate ethical standards in study design (see summary of published AI guidelines in Data S1). The importance and need for promoting transparency in standardized reporting guidelines in clinical research in aging has been previously introduced in the clinician-scientists transdisciplinary aging research (ClinSTAR) Enhancing the QUAlity and Transparent

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Summary

- Key points
  - With the rapid growth of AI precision medicine, older adults deserve special consideration when designing new technologies for testing given that those who are older represent a markedly heterogeneous population.
  - The EQUATOR network provides a 51-item CONSORT-AI checklist to help improve transparency specifically in reporting guidelines for randomized clinical trials using AI-based technology, but further design recommendations specific to older adults will help ensure their study inclusion and generalizability of results.
  - CONSORT-AI-5Ms recommendations may be one way to promote the development of safe, inclusive, unbiased AI-based clinical trials that hold the greatest potential to make meaningful improvements in the overall health of older adults.
- Why does this paper matter?
  - Amidst the wave of AI research that holds the potential for substantially transforming healthcare, there are no readily available guidelines to address older adults' needs using AI-based interventions in RCTs. Given the inherent complexity of aging, competing morbidities and potentially differing health care goals and priorities, minimum reporting guidelines for AI-based intervention trials tailored to the unique considerations of older adults are warranted to provide a generalizable framework for trial design, reporting, and reproducibility.

of Health Research (EQUATOR) network series [5]. The Consolidated Standards of Reporting Trials (CONSORT) AI extension [6, 7] is one that has been highlighted in this series, as it is developed specifically for randomized controlled trials (RCTs). CONSORT-AI was generated through consensus via the Delphi Method for clinical trials evaluating AI interventions to provide minimum reporting guidelines (14-item checklist) as an extension to the existing CONSORT 2010 guideline [8] (37-item checklist). Though currently there are few published RCTs involving AI in older adults, we anticipate that this will change soon.

Designing and conducting AI-based RCTs in older adults is challenging, even with the development of AI-extension guidelines such as CONSORT-AI. Historically, RCTs have often excluded older adults because of their heterogeneous characteristics [9–11]. Older adults are more likely to have multiple comorbidities, are sometimes unable to provide informed consent, and/or may have limited life expectancies. AI applications and precision health approaches, however, could allow for the inclusion of a wider array of older adults in research trials. This could lead to a more comprehensive understanding of treatment effects across a broader demographic, ultimately improving health outcomes for all ages. Moreover, AI may allow for tailored interventions that consider the unique health profiles of older adults, acknowledging their diverse needs and conditions, such as predicting chronic diseases [12], adverse outcomes [10], falls [13], and adherence to clinical programs [14]. However, to truly capitalize on the potential benefits of AI in clinical trials, researchers must address challenges related to data quality, ethical considerations, and the integration of AI interventions with existing healthcare infrastructures. Properly addressing these issues will be crucial to advance the use of AI in healthcare, especially for the benefit of older adults.

2 | Age-Friendly 5Ms

With an increasing aging demographic where the vast majority of care providers regardless of their subspecialty are expected to encounter older patients in their daily practices, geriatricians and health policy experts developed a disseminatable, cost-effective, and systematic approach to providing high quality care to older adults by establishing the Age-Friendly Health Systems initiative in 2015 [15]. Since then, key evidence-based elements that are known to improve outcomes in older adults have been incorporated into practice. These elements are the 5Ms: Mind, Mobility, Medications, Matters most [15], and Multi-complexity [16] (Data S2).

Older adults are inherently complex (and as such, atypical presentations of common conditions can also be found quite frequently) [17]. Geriatricians understand the concept that “if you have seen one 85-year-old, you have seen one 85-year-old.” Non-geriatricians, however, may not be familiar with considering the wide range of physical, cognitive, emotional, and social challenges unique to that individual (e.g., taking the 5Ms approach to caring for an older adult). Disease incidence, presentation, severity, prognosis, and treatment vary significantly between one older adult and another [18]. In an older demographic, it becomes crucial to adapt the focus of treatment to accommodate their unique circumstances, which may diverge significantly from the approaches typically applied to younger adults. In fact, studies have already shown the positive impacts of incorporating Age-Friendly care, including reduced readmission rates [19], improved delirium detection [19], improved nursing staff retention [19], and reduced cost [19–21]. One meta-analysis found an increase in survival and functional status when geriatric assessment is incorporated into cancer care [22]. More recently, incorporation of 5Ms in the inpatient setting for older adults with trauma also was found to be associated with positive outcomes, including reduction of delirium and improved time to first mobility [23]. These examples show how individual Ms of Age-Friendly care can lead to improved overall patient care and reduced healthcare cost and burden on the system; however, few have studied the effects of implementing all 5Ms together on health outcomes [21].

With more than 4000 hospitals and health care practices recognized by Institute for Healthcare Improvement (IHI) as Age-Friendly Health Systems Participants as of September 2024, [24] implementing the 5Ms into all aspects of older adult care has become increasingly widespread since its initial launch. AI-based interventions in clinical trials could also benefit from invoking the 5Ms framework to ensure a comprehensive understanding and approach to the multifaceted aspects of aging, which would be applicable then, to older adults across a wide spectrum of functionality (ranging from fully independent to requiring more assistance).

In this paper, our goal is to provide recommendations for the safe inclusion of older adults in AI-based research, specifically addressing conduct of RCTs. With this CONSORT-AI-5Ms recommendation, we hope to enhance the effectiveness of RCTs with AI interventions to include the older adult population by optimizing recruitment strategies, incorporating appropriate research data safely, equitably, and transparently while minimizing confounding factors in ways that are both scalable and sensitive to the needs of this demographic. Building upon CONSORT-AI guidelines to encompass 5Ms encourages Age-Friendly considerations for RCT design and intervention, resulting in AI technology developments that are safe, effective, and equitable for an aging global population.

3 | Consort-AI-5Ms Recommendations

In the following section, we discuss the CONSORT-AI extension and summarize the key considerations of how to better incorporate the 5Ms framework for older adults within this clinical guideline, specifically considering: (1) Background and objectives; (2) Participants; (3) Interventions; (4) Harms; and (5) Generalizability. In a subset of CONSORT-AI extension guidelines that are relevant for this discussion, we have also summarized point-by-point challenges in applying the guideline checklist items in older adults, and our recommendations to address these challenges (Table 1). For the complete CONSORT-AI extension guidelines, we refer the reader to the full articles [6, 7].

4 | CONSORT-AI-5Ms Introduction: Background and Objectives

The CONSORT-AI guidelines encourage researchers to describe how the AI intervention is intended to be used within the clinical pathway, detailing its purpose and the target users (e.g., healthcare professionals, patients, or the public). Specifically, researchers should question whether the underlying model employed in the AI-tool has ever been tested in older adults, and whether AI ageism could be present [25–28]. In the context of AI study design, the exclusion of older adults by age has been described as AI ageism, which has been reported in large datasets [25], such as the Face and Gesture Recognition Research Network (FG-NET) aging database [25, 26] that only included ages 0–69 and the Yoti facial age scan's training set [27] that included ages 13–60. Beyond age itself, AI ageism could result in the discrimination against older persons based upon neglecting age-related complexities of comorbidities and social context. For example, one AI hypertension home monitoring RCT [28] included participants with diverse race and ethnicity and ages up to 85 in the US, but excluded people with dementia, hearing impairment, terminal cancer, or severe kidney disease. To avoid age discrimination in AI study design, researchers must consider inherent biases that result from insufficient diversity, equity, and inclusivity in research data [29], especially when applying existing models to older adults in different care settings (e.g., community versus academic medical centers) [30].

5 | CONSORT-AI-5Ms Method: Participants

CONSORT-AI recommends researchers to state the inclusion and exclusion criteria for both the algorithm and the trial itself. Here, one should review additional factors beyond the basic demographics as people age differently based on environment, race, sex, socioeconomic status, and other factors. Some comorbidities which pertain to the 5Ms framework are common exclusion criteria for older adults (e.g., Mind: cognitive impairment, delirium, or depression; Mobility: physical impairment; Medications: polypharmacy; Matters most: burden on and availability of caregivers; Multi-complexity: frailty, social isolation, racial and ethnic minorities, oldest-old) [29, 31–33]. When applicable and able, we recommend that researchers consider and report:

- Mind: cognitive function, any associated diagnoses. If educational materials were introduced, document the method of delivery and how the research subject's understanding was assessed.
- Mobility: physical function, transportation, and assisted devices.
- Medications: review medication side effects and drug interactions.
- Matters most: identify the durable power of attorney (DPOA), surrogate decision maker, and any caregivers who might assist in study participation.
- Multi-complexity: consider frailty and other comorbidities as markers of vulnerability to possible adverse outcomes. Document any complex social relations, dynamics, and/or cultural beliefs that could impact consent, safety, and participation.

A key aspect of consideration specific to older adult participants when bringing AI interventions to RCT should include the participant's living situation. That is, to review any onsite or offsite requirements, and consider the challenges associated with the diverse care settings, care delivery, and treatment interventions in the older population (e.g., independent, assisted living, board and care, medical foster homes, and/or nursing home long-term care). This is particularly important as some AI models may not be applicable across different systems, especially since models are usually trained on data from a single setting [34]. Therefore, researchers should highlight the unique needs of the older adult population and clearly define the residential setting of the target population being studied.

6 | CONSORT-AI-5Ms Method: Interventions

When designing interventions, the use of 5Ms should be encouraged to guide the delivery method and duration of administration. For example, researchers can describe ways to overcome the common conditions in older adults that might limit adherence (e.g., visual impairment, hearing impairment,

TABLE 1 | CONSORT-AI-5Ms: Addressing potential challenges with recommendations for research in older adults.

CONSORT-AI extension [6, 7] items	Potential challenges	CONSORT-AI-5Ms recommendations
Introduction: Background and Objectives 2a: Explain the intended use of the **AI intervention** in the context of the clinical pathway	• Whether the underlying model employed in the AI-tool has ever been tested in older adults, and whether AI ageism could be present [25–28].	• Describe how the AI intervention is intended to be used within the clinical pathway, detailing its purpose and the target users (e.g., healthcare professionals, patients, or the public). • Consider inherent biases that result from insufficient diversity, equity, and inclusivity in research data [29].
Methods: Participants 4a: **Eligibility criteria** for participants: state the inclusion and exclusion criteria at the level of participants, and level of the input data	• Age—commonly used, but less helpful as older adults are a very heterogeneous population. • Sex & Race—people of different sex and racial groups can age differently. • Socioeconomic status- hard to measure but it should be controlled for as it is an important determinant of health. Some use insurance status or zip code as a proxy measure. • Commonly excluded participants: —*Mind*: cognitive impairment, delirium, or depression —*Mobility*: physical impairment —*Medications*: polypharmacy —*Matters most*: burden on and availability of caregivers —*Multi-complexity*: frailty, social isolation, racial and ethnic minorities, oldest-old.	• Include the age(s) of intended algorithm users (e.g., all adults or specific age criteria). • Include multiple care settings to represent multiple socioeconomic status (e.g., federal qualified health centers and private clinics). • Explain why certain population is excluded by the trial. • When applicable and available, include: —*Mind*: cognitive function, any associated diagnoses. If educational materials were introduced, document the method of delivery and how the research subject's understanding was assessed —*Mobility*: physical function, transportation, assisted devices —*Medications*: review side effects and drug interactions —*Matters most*: identify the DPOA, surrogate decision maker, and caregivers to assist in participation —*Multi-complexity*: frailty and co-morbidities as markers of vulnerability to possible adverse outcomes. Document any complex social relations, dynamics, or court involvement that impact consent, safety, and participation.
4b: Describe how the AI intervention was integrated into the **trial setting**, including any onsite or offsite requirements	• Access to geriatric care varies significantly across care settings. Not everyone has access to routine healthcare, specialized clinic, transportation, or internet, which can lead to underrepresentation, underdiagnosis, or delayed treatment. • Diverse residential settings and care delivery (e.g., independent, assisted living, board and care, medical foster homes and nursing home long-term care).	• Describe the training that's needed to use the AI intervention for provider, staff, and participants. • Consider user-centered designs and have focus groups with stakeholders for design feedback where possible. • Ensure to highlight the unique needs of the older adult population and be clear in defining the residential setting of the target population.

(Continues)

TABLE 1 | (Continued)

CONSORT-AI extension [6, 7] items	Potential challenges	CONSORT-AI-5Ms recommendations
Methods: Interventions 5(i): The interventions for each group with **sufficient details to allow replication**	• Adherence to treatment/intervention might be limited by 5Ms —*Mind*: visual impairment, hearing impairment, dentures, neuropathy —*Mobility*: transportation, falls —*Medication*: polypharmacy —*Matters most*: goals of care —*Multi-complexity*: frailty	• Describe ways to overcome the common conditions in older adults that might limit adherence. • Ensure the intervention does not increase frustration, dependence, or reinforce the impression of ineptitude but empower and increase autonomy [36].
5(ii): describe how the **input data** were acquired and selected for the AI intervention	• Input variables: often not well-defined, detailed description and knowledge of training data sometimes not available (e.g., inclusion or exclusion criteria).	• Define data input (e.g., images, text) as well as the source (e.g., public dataset). • State if the study involves all adults or mixed data including older adults in training and/or testing.
5(iii): describe how **poor quality** or unavailable input data were assessed and handled	• Age related biases [37] and AI: —*representation bias*: data underrepresents or misrepresents subsets of the population —*measurement bias*: data inaccurately reflects the variables —*omitted variable bias*: omitted data that indirectly affect age —*aggregation bias:* conclusions are drawn about individuals based on observations about a larger group.	• Consider variables that may change with aging (i.e., skin texture, pigmentation, unemployment, family members, and social media use), and state ways to overcome these biases (e.g., non-linear model, or weighted comorbidity scores) [41]. • Discuss why data were omitted and how it may affect the model's performance with reference to a different age group.
5(v): **specify the output** of the AI intervention	• The output could vary across different age or sex groups, and among various races and ethnicities.	• Assess performance among subgroups (e.g., different care settings or age groups, such as 60–69, 70–79, 80–89 years old).
5(vi): explain how the AI intervention's outputs contributed to **decision-making** or other elements of clinical practice	• The implementation of the AI intervention into different geriatric care settings might vary due to workflow and system culture.	• Consider the implementation and effects of the AI intervention on clinical staff and workflow in interdisciplinary team setting (*Multi-complexity*).
Results: Harms	• Lack of definition and detail regarding model optimization.	• Define model evaluation in detail (choice of validation metrics, e.g., sensitivity, specificity, PPV, NPV).
19: Describe results of any analysis of **performance errors** and how errors were identified, where applicable.	• Measured outcomes might not align with what matters most to older adults.	• Promote wider access (and increase transparency) to training datasets being used for evaluation.
Discussion: Generalizability 21: **Generalizability** (external validity, applicability) of the trial findings	• AI prediction ability depends on the representativeness of the data. The effectiveness of AI intervention depends on local variables including local data, patient demographics, and implementation factors. • AI models could be used in unintended ways.	• Define clear objectives as to how the model should be used, what it aims to evaluate and in whom, and provide mechanisms to externally validate its performance (diagnostic case–control or diagnostic cohort studies) [43].

dentures, neuropathy). Additionally, careful design would also ensure that the proposed innovation does not increase frustration or reinforce the impression of ineptitude that older adults may have with using new technologies. Indeed, one study reported that 1 week after exposure to a 1-month long robotic home intervention, older adults with mild cognitive impairment took longer to complete their usual living activities compared to their baseline function [35]. Thus, it is imperative that new technology is tested to ensure enhanced efficacy in its intended population, as opposed to introducing additional complexity. Technology should empower older adults, aid in promoting independence and autonomy [36], and not increase dependence.

Next, when handling input and output data of the AI algorithm, researchers should consider four age-related biases [37] that may arise:

- Representation bias: data underrepresents or misrepresents subsets of the population, such as smartphone data underrepresenting lower income [38], older adults [39], or different operating systems (e.g., iOS versus Android) [37].
- Measurement bias: data inaccurately reflects the variables, such as choosing the inaccurate proxy variable or wrong facial recognition for older adults. For example, Obermeyer et al. [40] found an AI model falsely predicted Black patients as healthier because the model used health costs as a proxy for health needs.
- Omitted variable bias: data that indirectly affect age were omitted due to incomplete understanding of age. For example, the 'Black-box' nature of many algorithms makes it difficult to figure out which variables were used and omitted. A study in emotion recognition found that gender was a confounding variable in age recognition due to the absence of data in older adults [35].
- Aggregation bias: conclusions are drawn about individuals based on observations about a larger group. For example, studies grouping older adults into a single category called '60+' results in lower accuracy that is not observed in other groups [39].

To overcome these biases, researchers should consider variables that may change with aging (e.g., skin texture, pigmentation, employment status, family members, and social media use), and state ways to overcome these biases (e.g., non-linear model or weighted comorbidity scores) [41]. Output data should also be assessed among subgroups, performing external validation with the target population (e.g., different age groups, 60–69 years, 70–79 years, 80–89 years) and updating the algorithm.

7 | CONSORT-AI-5Ms Results: Harms

When considering harm, researchers should not only transparently report results of any analysis of AI performance errors and how these errors were identified, but also consider that the measured outcomes might not align with what Matters most to older adults. For example, if autonomy and privacy are Matters most items for a given older adult, home monitoring AI interventions might be well received by one but not by another, and instead cause harm by affecting their autonomy and privacy. In one study for example, it was noted that older adults were less likely to use certain types of technology (e.g., fall detection or home monitoring systems) due to privacy concerns and embarrassment from potentially revealing sensitive information [42].

8 | CONSORT-AI-5Ms Discussion: Generalizability

The applicability of AI models depends on the representativeness of the data they are trained on. The effectiveness of AI intervention depends on local variables including local data, patient demographics, and workflow/implementation factors. When discussing the generalizability (external validity or applicability) of the trial findings, researchers should define clear objectives as to how the model should be used, what it aims to evaluate and in whom, and provide mechanisms to externally validate its performance. Two common external validation mechanisms are diagnostic case–control and diagnostic cohort studies with independent data from new settings [43]. In diagnostic case–control studies, researchers collect new samples with and without the target condition (e.g., lung cancer) separately to assess the algorithm's performance, prospectively or retrospectively. Diagnostic cohort studies, however, use real-world clinical data based on eligibility criteria (e.g., patients over 65 years old) to test the algorithm with performance often evaluated prospectively. Both validation approaches have been used, with neither being considered superior to the other, though some may argue that in general, prospectively cohort studies are stronger than case–control studies.

9 | Opportunities to Improve the Value of AI Randomized Controlled Trials for Geriatrics

In this work, we highlight some important considerations in improving the value of RCT design and AI interventions for geriatrics. As of 2024, few published RCTs contemplate special considerations for older adults. In the following section, we discuss other published studies in AI and geriatrics research with specific examples that involve addressing representation bias, the digital divide, potential misuse, implementation considerations, rooting in the 5Ms (Figure 1), and opportunities for increasing precision through n-of-1 trials. For avoiding age-related representation bias, researchers can consider including multi-feature data (e.g., longitudinal studies, insurance claims, or cancer databases) to better represent older adults [44] in addition to only using data from the electronic health record (EHR). An example of representation bias occurred when insufficient data on older adults and immigrants in the training data set led the model to under predict their risk of long-term unemployment [45]. Success in addressing age-related bias is shown by training the model to focus only on a few specific gait features rather than all features when detecting age-related gait changes [46]. Perhaps the most well-known representation biases have been identified in facial

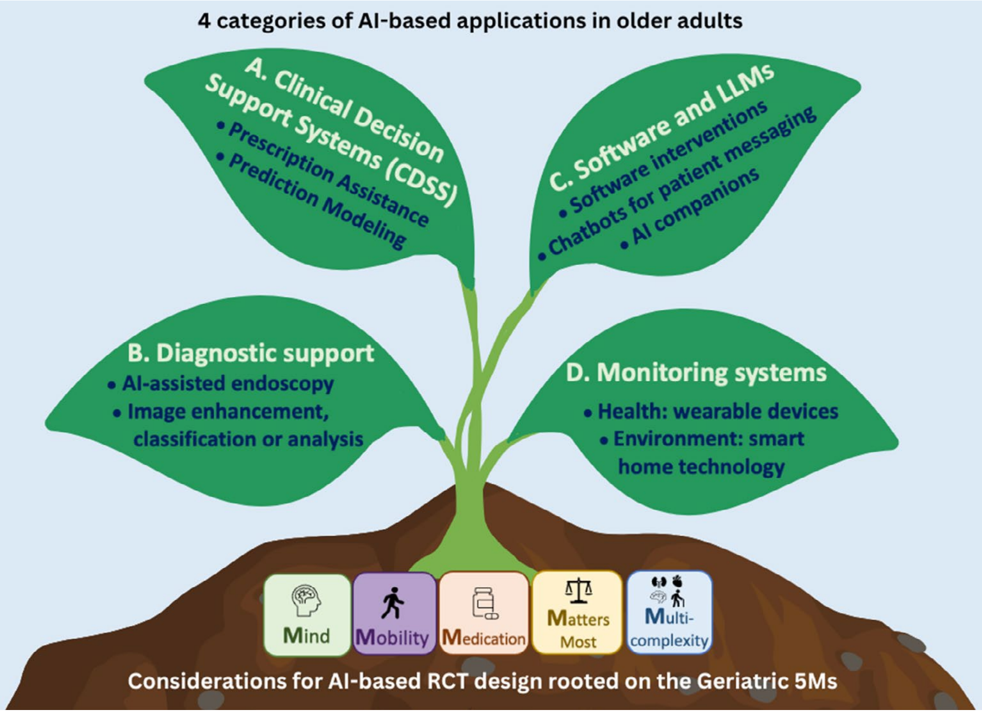

FIGURE 1 | Considerations for AI-based RCT design rooted on the Geriatric 5Ms. Conceptual framework depicting four broad categories of AI-based technology applications, and to consider development of these applications being rooted on the Geriatric 5Ms. Examples of the various categories of AI-based applications in research (represented in each leaf) are shown above, and with an overall aim of improving the lives of older adults, guided by the Age-Friendly Health Systems Geriatric 5Ms. A. Clinical Decision Support Systems (CDSS): Prescription assistance and prediction modeling; B. Diagnostic support: AI-assisted endoscopy for cancer detection and image enhancement, classification, or analysis; C. Software and large language models (LLMs): Software interventions, chatbots for patient clinical messaging, and AI-based companions; D. Monitoring systems: Health-wearable devices and environment-smart home technologies.

recognition systems where some perform poorly in identifying women with dark skin [25] or older adults [37]. To minimize representation bias, researchers can utilize (1) data augmentation, (2) extra training on marginalized groups, (3) training on individual demographics, and/ or (4) statistical adjustments [37]. Finally, besides recognizing potential biases, another way to increase accuracy in AI models is to have more comprehensive, diverse, and representative training data. In the United Kingdom, there are many initiatives for standardized geriatric databases from institutions [47], researchers [48], and trainees [49] to promote wider access and transparency for better geriatric research and collaboration.

Another potential concern in future AI-based RCT design is the heightened risk of social exclusion and falling behind due to a digital divide [37, 50]. Although more older adults are using and benefiting from technology, they remain the least likely age group to have access to and to utilize the internet [51], often due to physical (e.g., disability) or psychological barriers [37] (e.g., decreased cognition or confidence in the use of digital technology or anxiety over loss of data privacy) [52]. It is crucial to include older adults and/or their advocates with an interdisciplinary approach throughout the development and implementation of AI to provide user-centered designs and avoid a digital divide. Additional concerns include loss of autonomy [53] due to being reliant on AI itself. For example, automated pill boxes and reminders for medications may preclude older adults from managing medications on their own even if they were previously doing so independently. In home-monitoring technologies, it was reported that while older adults do want control over which information is shared with family/caregivers, little could be done to customize "user-centric/user-specific" scripts [54]. Considering cognitive function as a patient characteristic, researchers should record the method of information delivery and assessment of user understanding of the AI models [55, 56], in addition to documenting decision-making capacity. In a fall prevention RCT [57], researchers were able to include participants with dementia if they had a proxy who was willing to provide consent and assist them during the trial.

Next, researchers should be aware of potential misuses of AI models in older adults. Two important issues to consider are potential safety risks due to lack of clinical validation data and ethical concerns. Notably, while there are currently over 600 Food and Drug Administration (FDA) approved AI-based tools known to date [58], insufficient attention has been given to how these devices might benefit and/or harm older users. This may be secondary to the limited availability of post-marketing surveillance/safety data. As such, of the FDA approved devices, only about half (56%) are clinically validated, and within that subset, a mere 4.2% are validated via RCT [59]. Portacolone et al. [60] highlighted some of the ethical concerns that arose with an artificial robot companion in older adults with cognitive impairment. Two illustrative scenarios showed how older adults with cognitive impairment could be deceived by: (1) individuals with access to the robotic pet interaction data who knowing the individual would easily be able to obtain sensitive information such as financial planning details; or (2) when an older adult could be monitored unknowingly, falsely believing that they have requested to have the pet in "sleep mode." Conversely, AI-based technology may be used to overcome some of these potential misuses, as has been proposed by other researchers who work on detecting elder abuse in the emergency department setting [61].

With regards to AI implementation, researchers need to assess the workflow and system culture at each site because successful implementation of AI in geriatric care requires adequate staff training and adjustments to traditional workflows. Lukkien et al. [62] reviewed 25 papers demonstrating responsible innovation in using AI in long-term care settings. The three main overarching themes to ensure responsible innovation were to: (1) involve older adults in the design and implementation of AI tools, (2) address ethical challenges such as privacy, transparency, and autonomy, and considering diverse user abilities, and (3) ensure that AI technologies are adaptable to various care settings.

In considering AI-based tools in older adults, we should, to the best of our abilities, have a strong foundation based on incorporating the 5Ms of geriatrics. AI-based tools developed for potential use in geriatric medicine by and large, can be classified into four broad categories [63] (Figure 1). Martindale et al. [4] reviewed published AI tools that followed CONSORT-AI guidelines [6, 7], introducing some of these categories, that here we proposed be rooted in the 5Ms context. The first category includes those tools that fall under clinical decision support systems (CDSS) (Figure 1A), including prescription assistance [64] and prediction modeling [65]. The second category is diagnostic support aids that can be procedure based, or image based (Figure 1B). Software and large language models (LLMs) comprise the third category with examples including software interventions for patient education, and LLMs that utilize natural language processing (e.g., chatbots, AI companions) (Figure 1C). The final category is monitoring systems for both health and home environment (Figure 1D).

With medical advances and precision medicine, the n-of-1 trial or implementation science [66] may become the future. In fact, some have argued that the RCT is not the best way to evaluate AI technologies [67]. Some concerns include difficulties in maintaining the consistency of AI algorithms during the trial with continuous learning from expert clinician input, unreliable comparison to a small group of experts, and the concern that clinicians might have bias if unblinded during trial. However, the scope of AI related research is broad, and certain intervention studies that incorporate AI may be best tested using RCT. For example, comparative studies of current modalities of diagnosis or treatment may be best tested using double-blinded RCT designs, such as computer-aided detection of adenoma in colonoscopy [68]. Regardless of the AI study type, we posit that 5Ms will serve as a useful guide to consider that incorporates the needs of older adults.

10 | Conclusion

The promise of AI technologies should be inclusive of older adults whose Multi-complexity might benefit most from such interventions that have the potential to deliver highly personalized, precision-based medical care. However, the CONSORT-AI extension poses potential challenges in its application to older adults due to the inherent increased heterogeneity of almost any biological or physiological characteristic. By incorporating the 5Ms with the CONSORT-AI extension guidelines in designing AI RCT's, researchers can better address the complex dimensions of aging, regardless of whether the adults are independent or require some level of assistance.

Author Contributions

Caroline Park, Vijaytha Muralidharan, and Deborah M. Kado conceived the original concept for the series. Betsy Yang, Caroline Park, and Deborah M. Kado drafted and revised the manuscript. All authors revised and approved the final version for publication.

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Conflicts of Interest

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Supporting Information

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