COMUNICAÇÃO E QUALIDADE DE RELATO DE RESULTADOS DE PESQUISA

Tese

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“But even the greatest guidelines or constitutions in the world cannot succeed unless we have the practical tools to make them work for everyday people in their everyday lives”.

Communications Handbook for Clinical Trials

SUMÁRIO

LISTA DE ABREVIATURAS E SIGLAS

CONSORT - Consolidated Standards of Reporting Trials

ECRs - Ensaios Clínicos Randomizados

EQUATOR - Enhancing the QUAlity and Transparency Of health Research

PPI - Patient and Public Involvement

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PRISMA-P - Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols

PROSPERO - International prospective register of systematic reviews

REBEC - Registro Brasileiro de Ensaios Clínicos

SPIRIT - Standard Protocol Items: Recommendations for Interventional Trials

STROBE - Strengthening The Reporting of Observational Studies in Epidemiology

SWAT - Study Within A Trial

RESUMO

A presente tese tem como objetivo explorar e dar visibilidade às práticas de transparência nos diferentes processos de construção de pesquisa e delineamentos de estudos, com destaque para ensaios clínicos. A revisão da literatura contempla informações sobre iniciativas e recomendações que contribuem para uma adequada comunicação e qualidade de relato de pesquisa por diferentes partes envolvidas, principalmente no nível de divulgação de resultados de pesquisa aos participantes e pesquisadores. Em complemento, são apresentados dois artigos com as seguintes temáticas: 1) análise do retorno de dois formatos de entrega de resultados individuais a participantes de pesquisa; 2) avaliação da qualidade de relato de resumos de ensaios clínicos sobre intervenções de atividade física usando o CONSORT para resumos. O primeiro estudo apresentou perspectivas positivas dos participantes em relação a compreensão, satisfação e impacto psicológico dos diferentes formatos de entrega. O segundo estudo demonstrou aderência subótima aos itens recomendados pelo CONSORT para resumos.

Palavras-chave: comunicação, divulgação, resultados de pesquisa, ética em pesquisa, ensaio clínico.

ABSTRACT

This thesis aims to explore and give visibility to transparency practices in different development processes of research construction and research study designs, with emphasis on clinical trials. The literature review includes information on initiatives and recommendations that contribute to an adequate communication and quality of reporting of research by different stakeholders, especially regarding the results for participants and researchers. In complement, two articles are presented with the following themes: 1) analysis of the return of two formats for delivering individual results to research participants; 2) evaluation of the quality of reporting of clinical trial abstracts on physical activity interventions using the CONSORT for Abstracts.The first study presented positive perspectives from participants regarding understanding, satisfaction and psychological impact of different delivery formats. The second study demonstrated suboptimal adherence to the items recommended by the CONSORT for abstracts.

Keywords: communication, disclosure, results research, research ethics, clinical trial.

1. INTRODUÇÃO

A transparência em pesquisa, amplamente debatida na comunidade científica, engloba diferentes princípios e iniciativas que visam contribuir com o rigor, qualidade e clareza dos processos de pesquisa, tendo como objetivo o avanço do conhecimento científico para diferentes públicos-alvo (1–4). A comunicação efetiva é uma das práticas que viabiliza maior transparência, e que deve ser incluída desde a elaboração da questão da pesquisa até a disseminação dos achados, contemplando as diferentes esferas envolvidas no processo de construção da ciência (5,6).

Neste sentido, o *Patient and Public Involvement* (PPI) nas diferentes etapas da pesquisa norteia os princípios de transparência e integridade com foco em participantes de pesquisa e públicos envolvidos, levando em consideração suas preferências e perspectivas na construção e disseminação do conhecimento científico (7,8). Assim, no nível dos participantes e público leigo, o processo de comunicação da pesquisa se inicia cada vez mais com a participação do usuário na identificação de temas prioritários, definição da pergunta e identificação dos desfechos críticos e importantes, seguido de um melhor acesso às pesquisas e, subsequentemente, de um consentimento ético com informações claras sobre os objetivos, avaliações, benefícios, riscos e direitos relacionados à pesquisa (7,9). Estima-se que uma comunicação efetiva entre os pesquisadores e participantes seja mantida durante todo o processo de pesquisa até a finalização do estudo (5,7), com práticas de disseminação dos resultados agregados e individuais, valorizando o papel central daqueles que dispõem do seu tempo, das suas histórias e dados, e de seus corpos para potenciais benefícios da sociedade (10–12).

Do mesmo modo, ao se referir à comunidade científica, com o intuito de dar visibilidade e melhorar a qualidade da comunicação de pesquisa, a incorporação de práticas que incluem pré-registro e publicação de protocolos são iniciativas que reportam o planejamento e a condução dos diferentes processos de pesquisa, contribuindo na avaliação da validade interna e externa dos estudos (2,4,13–15). Relatos completos, compartilhamento de dados e acesso aberto também são

estratégias relevantes para o progresso e fortalecimento da ciência tanto no meio científico como na sociedade, pois visam maior reprodutibilidade dos achados da pesquisa (16–20).

Considerando que a pesquisa clínica consiste de atividades complexas e multidisciplinares, relatórios claros e concisos são necessários para tomada de decisão baseada em evidência, principalmente em ensaios clínicos randomizados (ECRs), os quais são considerados como um delineamento padrão-ouro para tomada de decisões de intervenções terapêuticas e preventivas (20). Desde modo, crescentes iniciativas contemplam recomendações e sugestões para a prática da disseminação de resultados aos participantes da pesquisa (10, 21–23). Além disso, a metodologia *Study Within A Trial* (SWAT) foi lançada para avaliar ou explorar alternativas de entregar ou organizar diferentes processos metodológicos de ensaios clínicos, contribuindo para fornecer evidências de como melhorar os processos de pesquisa, dentre eles o relato dos resultados (24). No entanto, ainda são escassos os estudos com essa metodologia e, de forma geral, dados da literatura reportam mais sobre a entrega dos resultados agregados a diferentes perfis de população do que informações que visam avaliar a qualidade e os efeitos da entrega de resultados individuais (12), principalmente em populações idosas. Barreiras logísticas, financeiras e de impactos emocionais podem ser identificadas como limitadoras desse processo (25), porém, cabe destacar que tais barreiras variam conforme o tipo de estudo e características da população, incluindo diagnóstico, contexto de saúde, educação e literacia em saúde (12).

De modo semelhante, tendo em vista que os resumos são geralmente a parte mais lida de um artigo científico, e que muitos leitores baseiam-se nas suas informações para avaliar a validade e aplicabilidade dos achados da pesquisa (26,27), a adoção de práticas para maior qualidade de relato científico nesta seção deve ser implementada primariamente por autores e editores. Neste sentido, com o intuito de melhorar o relato de resumos, o grupo *Consolidated Standards of Reporting Trials* (CONSORT) lançou em 2008 a extensão CONSORT para resumos, que contempla itens essenciais das diferentes etapas da pesquisa a serem reportados com maior

clareza e detalhes (27). Porém, mesmo com a melhora da descrição de alguns itens ao comparar resumos publicados antes e depois da extensão CONSORT, as informações em algumas disciplinas ainda são consideradas subótimas (28–31). Além disso, estudos mostram inconsistência de informações dos resumos com os relatórios completos (32,33), o que prejudica a interpretação e ameaça a confiabilidade e validade das evidências publicadas, podendo ocasionar uma tomada de decisão imprecisa ou incorreta sobre os efeitos de uma determinada intervenção (34,35).

A partir dessas informações, destacamos a importância da comunicação efetiva dos achados de pesquisa com entrega de relatos completos e precisos, seja no nível da interação com participantes de pesquisa, ou no meio científico, o que fortalece e propicia o progresso da ciência (12,20,27). Assim, traduzir as informações dos resultados de ECRs, conforme preferências e necessidades das partes interessadas, contribui para otimizar a difusão de conhecimento e potencializar a melhoria da implementação de metodologias e resultados para a pesquisa e saúde. Desta forma, embora exista um movimento para mais transparência nas práticas de pesquisa em ensaios clínicos na área do exercício e atividade física (13,36), não identificamos estudos que relatem sobre a transparência e qualidade de informações nos resumos. De mesmo modo, ainda que os resultados individuais possam ser compartilhados com os participantes do estudo, não temos conhecimento de qualquer pesquisa ou esforço para avaliar e identificar a entrega dos resultados neste campo da ciência. Portanto, a presente tese buscou sintetizar as recomendações e estratégias que contribuem para uma adequada comunicação de resultados e qualidade de relato em diferentes delineamentos de estudo, com ênfase em ensaios clínicos. Os artigos que compõem a tese visam explorar as lacunas de comunicação dos resultados de ensaios clínicos no nível de participantes, a partir da avaliação de dois formatos de entrega de resultados individuais, e no nível de comunidade científica, a partir da análise da qualidade de relato de resumos na área do exercício e atividade física usando o CONSORT para resumos.

2. REVISÃO DA LITERATURA

Comunicação na pesquisa

A transparência em pesquisa refere-se ao processo de tornar claro e acessível a produção e o relato das diferentes fases da pesquisa às partes interessadas (2,4). Considerada um princípio científico, quando em conjunto com os princípios de confiabilidade, honestidade, respeito e responsabilidade ética, norteia e fortalece a prática de integridade em pesquisa (1). No processo de construção da pesquisa, a comunicação é um dos pilares primordiais para mais transparência, considerada uma interface essencial que abrange diferentes esferas e públicos-alvo como órgãos governamentais, financiadores, instituições de ensino e pesquisa, pesquisadores, gestores de saúde, participantes e comunidade geral (5,6). Deste modo, a comunicação na pesquisa vai além de modelos acadêmicos tradicionais como periódicos, livros e conferências, ela envolve colaborações interdisciplinares, com destaque crescente para a implementação de práticas que possibilitam o PPI, tanto nos estágios da construção da pesquisa como na tomada de decisões compartilhadas (7,8,37,38). Em vista disso, o desenvolvimento e a implementação de práticas para uma disseminação e comunicação ampla e inovadora são recomendadas como princípios de transparência e integridade na pesquisa (5,39).

Com o intuito de aumentar o impacto da pesquisa sobre a ciência e a sociedade (5,40), a comunicação efetiva é fundamental pois possibilita a compreensão das informações e a tomada de decisão compartilhada, dá suporte para o estudo atual e futuras pesquisas, contribui para o desenvolvimento de diretrizes e políticas nacionais, bem como para a implementação de financiamentos de intervenções de saúde, e oferece fontes sólidas de informações para os diferentes meios de comunicação (5). Sugestões reportadas na literatura fornecem aos pesquisadores e partes interessadas métodos e ferramentas que visam contribuir para adoção de práticas de uma comunicação e disseminação efetiva especialmente em ensaios que avaliam novos medicamentos ou intervenções em um ambiente comunitário (5). Dentre elas,

destacam-se: a importância de conhecer os interesses e necessidades do público-alvo e incentivá-los como parte integrante do fluxo de trabalho de pesquisa, definir os objetivos e direcionar as mensagens principais, tornar a disseminação atraente por meio de diferentes recursos audiovisuais, usar linguagem acessível e simples, sem uso de jargões científicos ou termos médicos ou de saúde pública complexos, e adotar os princípios de ciência aberta (5,40,41). Planejar as atividades e definir estratégias viáveis e eficazes considerando os diferentes recursos para divulgar os resultados, seja por meio de conferência científica, periódico científico, mídias sociais ou encontros com os participantes e público geral, também é um elemento chave no processo de colaboração e comunicação de pesquisa (5). Como forma de operacionalizar questões de pesquisa vinculadas ao delineamento de ECRs, estudos SWATs são sugeridos para avaliar, explorar e preencher lacunas relacionadas aos processos metodológicos, sendo um desses o processo de disseminação dos resultados da pesquisa, contribuindo com mais evidência e clareza nesta etapa (24).

No que se refere à interface de comunicação entre instituições e pesquisadores com os participantes de pesquisa, cabe destacar que as práticas de PPI podem se manifestar no planejamento de projetos, com a elaboração de uma questão de pesquisa e identificação de desfechos relevantes de acordo com a perspectiva do paciente, na supervisão e monitoramento dos instrumentos de avaliação e dados de pesquisa, na análise e interpretação da disseminação dos resultados gerais e dos próprios participantes, na avaliação e implementação dos diferentes processos de pesquisa, e na experiência do participante ao longo do estudo (7,8). Tais práticas fortalecem a qualidade, eficiência e clareza na entrega das informações (7,8), e tornam a pesquisa mais relevante e atraente a partir de um diálogo bidirecional (42,43). Diante disso, como forma de apoiar o PPI em pesquisa e facilitar profissionais e pesquisadores neste processo, Greenhalgh e colaboradores sintetizaram algumas estratégias focadas em: (1) explorar os princípios de valores e ética; (2) definir tópicos de pesquisa a serem priorizados; (3) maximizar recrutamento e adesão ao estudo; (4) orientar a redação e avaliação crítica dos relatórios apresentados a diferentes audiências e (5) assegurar a transparência e responsabilidade pública a partir de

parcerias colaborativas entre pesquisadores e leigos ou organizações. No entanto, os autores destacam a importância de avaliar, adaptar e desenvolver estratégias próprias baseadas em evidências de acordo com o tipo de estudo e público envolvido (38).

A profundidade e a extensão das informações que os participantes recebem sobre os objetivos e métodos da pesquisa requer melhorias, pois nem sempre são claras e suficientes (7,9). Geralmente essas informações são disponibilizadas antes do participante consentir entrar no estudo, por meio do documento de consentimento informado, que deve compor os objetivos do estudo, procedimentos, benefícios, riscos e direitos de forma específica e fácil de entender (7). Desse modo, mudanças são sugeridas na estrutura e distribuição das informações contidas no documento, bem como propostas para entrega de forma coletiva e com uso de recursos audiovisuais (9,44,45), tendo como finalidade melhorar a compreensão do estudo e a comunicação com os participantes, possibilitando uma tomada de decisão autônoma e consciente.

Estabelecer uma boa comunicação com os participantes ao longo do estudo, mantendo-os informados sobre os processos de pesquisa e esclarecendo dúvidas de forma simples também é essencial (5). Essa comunicação se estende à disseminação dos resultados, os quais podem ser de vários tipos: resultados urgentes, resultados de rotina, ou resultados agregados e individuais ao final do estudo (21). Embora os resultados geralmente sejam apresentados em conferências e publicados em jornais, e poucos documentos forneçam orientação abrangente aos pesquisadores sobre as responsabilidades de uma comunicação centrada no participante durante a condução do estudo (5,21–23), existe um coletivo e crescente interesse na disseminação e comunicação dos resultados agregados e individuais (10,12,37,46,47). Tais resultados representam, respectivamente, dados sintetizados com descobertas gerais dos grupos (23), e informações individuais dos diferentes procedimentos, avaliações e testes realizados durante a participação do estudo (22).

As práticas de comunicação e disseminação centrada no participante de pesquisa são consideradas um imperativo ético e de respeito com os voluntários de pesquisa que dispõem do seu tempo e se colocam em risco para contribuir com o conhecimento científico e com a saúde pública (5,7,10,12,21,23). Do mesmo modo,

visam aumentar a transparência e oportunidades de aprendizagem, o que reflete na educação e literacia científica e em saúde (5,37,47), possibilitando a compreensão dos participantes sobre a importância do seu papel ao longo do estudo. Também podem gerar maior satisfação, entendimento e engajamento do participante (10,22,23,48), e influenciar no seu poder de escolha em relação a sua condição de saúde e cuidados, sendo útil no diagnóstico, tratamento ou prevenção de doenças (10,48,49). A intenção de retornar os resultados de pesquisa aos participantes deve ser descrita no documento de consentimento, seguido de um plano de compartilhamento, garantindo assim que os participantes estejam cientes da oportunidade de receber os resultados, e decidam como e a quem esses resultados serão comunicados no final do estudo. Cabe também aos pesquisadores informar os possíveis benefícios e riscos, e esclarecer os participantes sobre o direito em decidir receber ou não os resultados da pesquisa clínica (10,23,25).

Embora a maioria dos pesquisadores da área da saúde relate que os resultados devem sempre ser compartilhados (25,47) e, de modo semelhante, o desejo dos participantes em receber os resultados de pesquisa clínica seja relatado em diferentes perfis e condições de saúde (12,37,47,50), essa prática é pouco estimulada pelos órgãos de fomento e comitês de ética (50). Estudo com 1818 autores identificou que apenas 27% dos pesquisadores divulgaram os resultados e 13% planejaram divulgar (50). Entre um total de 3381 participantes de pesquisa, e em torno de 33% dos participantes mencionaram receber os resultados dos estudos os quais participaram (46,51). Esses dados refletem a retenção de informações, e podem estar relacionadas às barreiras logísticas, financeiras e de literacia em saúde, bem como ao baixo incentivo e a incerteza sobre o tipo de informação, o formato de entrega e o estilo de comunicação a ser usado de acordo com as perspectivas dos diferentes perfis da população, e os possíveis riscos de má interpretação e impactos emocionais como estresse psicológico, ansiedade e tristeza (12,25,37,48,52). No entanto, algumas iniciativas internacionais buscam financiar projetos que abordem as lacunas de conhecimento no processo de comunicação e disseminação de resultados de pesquisa (53,54), contribuindo para a redução de uma das barreiras da disseminação.

Além disso, embora não exista um método ou abordagem padrão para o retorno dos resultados de pesquisa aos participantes, e variações quanto a preferência do formato de entrega são reportados conforme o perfil e faixa etária do público-alvo (12,37,47,48,51,55,56), orientações sobre o conteúdo e a estrutura são disponibilizadas para facilitar e guiar os pesquisadores à condução dessa prática (5,10,21–23), corroborando com o direito e o desejo dos participantes em receber os seus dados mesmo diante de resultados negativos ou com um possível risco de impacto emocional negativo (12,48).

No nível de comunicação de resultados agregados aos sujeitos da pesquisa, um resumo com linguagem simples, neutra e objetiva deve ser elaborado, planejado e executado incorporando os princípios de literacia em saúde em conformidade com as normas institucionais, políticas do patrocinador e do investigador (23). Sugere-se que a entrega dos resultados seja no prazo de até um ano após a conclusão do estudo e que as organizações determinam os métodos mais adequados de entrega, bem como a infraestrutura e os recursos, incluindo custo e tempo, e levando em consideração as características, necessidades culturais e expectativas da população do estudo (23). Já a nível de resultados individuais de ensaios clínicos, um plano deve ser realizado e revisado para garantir os direitos e o bem-estar dos participantes, levando em consideração suas preferências e a utilidade médica, social e pessoal dos resultados divulgados (22). Cabe destacar que o retorno dos resultados individuais não pode substituir os cuidados e conselhos clínicos apropriados. Sugere-se também que os participantes sejam informados sobre o tempo e o processo de retorno dos resultados, os quais devem ser entregues em momentos que mantenham a integridade e a capacidade da pesquisa de atingir os objetivos, sem comprometer a segurança e bem-estar dos participantes (22).

Conforme dados da literatura, explorar as perspectivas, preferências e necessidades dos participantes e público envolvido é uma forma de contribuir para uma comunicação clara entre pesquisadores e participantes, além de valorizar o seu papel fundamental no processo de construção da pesquisa (7,12,21,37). Assim, pesquisas voltadas a esse tema são necessárias, uma vez que a prática de

disseminação de resultados individuais é mais frequente em estudos envolvendo pesquisa genética ou câncer (12,48,57,58), e quando disseminada para outras áreas, contemplando perfis de população idosa (37,56), por exemplo, ainda que de forma escassa, o relato é dos dados agregados (25,37,50,55,56).

Qualidade de relato de pesquisa

Diversos guias e ferramentas de relato são disponibilizados para diferentes delineamentos de estudo com o objetivo de fortalecer e melhorar os princípios de transparência e integridade (59), contribuindo para a reprodutibilidade dos achados (2,39,60). Pesquisadores, instituições, financiadores, revisores e editores de periódicos são responsáveis pela implementação de tais práticas (1,61), as quais devem ocorrer desde o processo de planejamento até a disseminação dos achados de pesquisa (4,34).

Dentre as recomendações relacionadas ao planejamento de estudos, os pré-registros e a submissão de protocolos têm ganhado destaque (4,13). Neste contexto, o registro de estudos em plataformas abertas, como o *ClinicalTrials* ou Registro Brasileiro de Ensaios Clínicos (ReBEC) para delineamento de ensaios clínicos, e o PROSPERO para revisões sistemáticas, permite a disponibilização de informações para possíveis participantes e evita a duplicação desnecessária de esforços e gastos de pesquisa no meio científico (62). Enquanto os registros contemplam informações mínimas do estudo, os protocolos visam detalhes mais específicos com descrições do desenho, planos de análise e intervenções, sendo base para o planejamento, condução, relatório e avaliação do estudo (14). Iniciativas como o SPIRIT (14) e PRISMA-P (15) apresentam recomendações para a publicação de protocolo de ensaios clínicos e revisões sistemáticas com metanálise. Para demais desenhos de estudos, as principais questões a serem abordadas na elaboração de um protocolo também estão disponíveis para consulta e aderência dos pesquisadores e revisores

(63). Os processos de registro e desenvolvimento do protocolo devem ser realizados e disponibilizados antes do início do estudo, pois possibilitam aos leitores uma análise de transparência em relação ao que foi planejado e realizado, além de sinalizar e contribuir para evitar viés de publicação e relato seletivo, os quais se referem a descrição de dados e resultados mais favoráveis ou significativamente estatísticos (2,64,65).

Na elaboração de artigos, os quais continuam sendo o núcleo da comunicação de pesquisa, as diretrizes como CONSORT, STROBE e PRISMA fornecem recomendações para relatórios padronizados de ensaios clínicos, estudos observacionais e revisões sistemáticas, respectivamente, com o objetivo de melhorar a qualidade de relato das etapas de pesquisa e, consequentemente, das informações disponibilizadas aos diferentes públicos (16,17,20). Tais recursos são apresentados de forma conjunta pela Rede EQUATOR (Enhancing the QUAlity and Transparency Of health Research) (59), iniciativa que visa melhorar a confiabilidade, utilidade e impacto com as publicações de pesquisa em saúde (66). Além disso, a implementação da cultura de compartilhamento de dados é uma prática recomendada e de forte incentivo para os pesquisadores garantirem uma melhor documentação dos seus dados e relatarem informações precisas, robustas e transparentes (4,19,66). Quando realizada, permite a reprodutibilidade dos achados, a exploração de novas análises e ideias não previstas pelos autores, bem como o uso de dados secundários para fins de avanço científico e educacional, minimizando a coleta de dados duplicados e reduzindo os custos de pesquisa (67–69).

Seguindo os princípios de transparência, a disponibilização gratuita dos achados de pesquisa, por meio de repositórios abertos ou por implementação de políticas editoriais para acesso aberto, vem sendo cada vez mais debatida pela comunidade científica, agências de fomento, políticas institucionais e editoriais (18). No entanto, apesar do surgimento de diferentes modelos de publicação de acesso aberto, muitos periódicos operam por assinatura ou taxas para leitura de artigos científicos, o que restringe o acesso dos leitores às informações completas, claras e transparentes (18,34,70). Em países como o Brasil, por exemplo, onde a produção

científica é financiada por agências de fomento público, o acesso às revistas pagas também é restrito. Deste modo, os resumos - por serem a única parte indexada nas bases de dados eletrônicas (71) - são a única parte disponível para consulta aos leitores, levando a maioria destes a considerarem apenas essa seção do artigo (26,72). Assim, resumos incompletos ou de baixa qualidade de relato podem fazer com que os indexadores de banco de dados cometam erros de indexação, o que posteriormente dificulta a identificação desses estudos aos possíveis leitores; além de ocasionar desinteresse pela leitura do artigo completo seja a nível de avaliação dos editores, revisores ou público geral (72,73). Resumos bem estruturados e informativos são aqueles que fornecem detalhes suficientes para agilizar a classificação do artigo como relevante ou não para o trabalho clínico ou interesses de pesquisa dos diferentes leitores (73). Portanto, guias e recomendações específicas estão disponíveis para melhorar a qualidade e transparência da entrega de informações em resumos de diferentes tipos de estudo (27,73,74). No entanto, ainda há espaço para melhorias no processo de condução, tradução e disseminação dos resultados (4,12,13,75).

Para ensaios clínicos, por exemplo, resumos bem escritos e estruturados com informações precisas do texto completo são recomendados pelos Editores de Revistas Médicas e pelo grupo CONSORT (20,27,71). Como proposta de melhorar o relato dos resumos de ensaios clínicos em artigos e conferências, foi desenvolvido a extensão do CONSORT para resumos, a qual contempla itens chaves a serem considerados para reportar as principais informações e resultados da pesquisa (27). Os itens devem incluir detalhes dos objetivos do estudo, desenho do ensaio, participantes, intervenções destinadas a cada grupo randomizado e seu impacto sobre os resultados e danos, conclusões, nome e número de registro do ensaio, e fonte de financiamento. Estudos compararam a qualidade dos resumos de artigos antes e depois da extensão para resumos (28–31) e identificaram que os detalhes sobre a intervenção, objetivos e conclusão foram bem reportados em ambos os períodos (28,29), além de melhorias observadas na descrição de alguns itens metodológicos

após a publicação da extensão. No entanto, de forma geral, a qualidade do relato e a adesão a maioria dos itens sugeridos ainda permanece baixa (28–31,76).

Além disso, mesmo com algumas revistas endossando a extensão de resumo nas instruções aos autores para facilitar a transparência e comunicação de ensaios clínicos (77), a aderência a um resumo estruturado e aos itens sugeridos é incompleta e variável, com poucas informações dos métodos e resultados do estudo em diversas áreas (31,75,76,78), mesmo quando é sugerido o limite de palavras considerados suficientes - 250 a 300 palavras - para abordar todos os itens da lista do CONSORT para resumos. De modo semelhante, relatos seletivos de resultados e inconsistência de informações são observadas quando os resumos são comparados ao texto completo (32,33,79,80). Tais dados são preocupantes, pois os resumos são a "impressão inicial" de um artigo de pesquisa, e uma das partes mais importantes para editores, revisores e leitores (72,73), pois muitos apenas leem ou tem acesso a essa parte do artigo, e - apesar de inadequado - tomam decisões a partir das informações reportadas nesta seção (26,27). Assim, resumos claros, transparentes e precisos que refletem o que foi incluído no artigo completo são importantes para que os leitores entendam o que foi feito e avaliem a confiabilidade e a relevância dos achados, fazendo uso dos resumos de forma mais efetiva (27).

Portanto, a partir das informações abordadas nesta revisão, destacamos que a transparência e integridade em pesquisa, seja ela clínica ou não, consiste de atividades multidisciplinares, às quais fortalecem as tomadas de decisões por profissionais de saúde, financiadores, editores, revisores e público em geral, sendo responsável por melhorias nos diferentes contextos de saúde. Desta forma, avaliar e implementar estratégias de qualidade para comunicação e disseminação dos resultados de ensaios clínicos é fundamental para garantir clareza, reprodutibilidade e impacto na comunidade científica e na sociedade, o que contribui para o progresso da ciência transparente e acessível a todos. Assim, na seção que segue, serão apresentados dois artigos que visam explorar tais processos na área do exercício e atividade física; destacamos a importância de investigar sobre esse tema em uma área que contribui para prevenção e tratamento de diversas condições de saúde,

dentre elas, doenças cardiovasculares (81,82). A partir disso, pretendemos fortalecer práticas que visam comunicar de forma otimizada o conhecimento aos participantes de pesquisa e aos pesquisadores e gestores de saúde, facilitando o uso eficaz de resultados de pesquisa e contribuindo para a melhoria de contextos clínicos a nível individual e global.

3. JUSTIFICATIVA E OBJETIVOS

Diante das informações observadas na literatura com escassa elaboração e implementação da entrega dos resultados individuais com foco no público-alvo, e baixa qualidade de relato em resumos de ensaios clínicos em diversas disciplinas, identificamos a necessidade de explorar práticas de comunicação e disseminação que visam maior transparência e integridade na área do exercício e atividade física. Os artigos que compõem a presente tese têm como objetivo dar visibilidade aos resultados de ensaios clínicos, investigando ambos os eixos de comunicação científica: (1) ao nível de participantes, com entrega de resultados individuais após participação de estudo com intervenção de estilo de vida; e (2) ao nível de pesquisadores, com análise da qualidade de relato de resumos de artigos baseados em intervenções de atividade física.

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5. ARTIGO 1

Perspectives of older participants on the delivery of individual results: Study Within A Trial (SWAT) hosted by the HAEL Study

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Abstract

Background: Communicating and disseminating individual results to research participants is an ethical imperative, however, this practice is still unusual. In the present study, we investigated two delivery formats of individual results to older participants on the perspectives of understanding (main outcome), satisfaction, and short-term psychological impact. **Methods:** This Study Within A Trial (SWAT) is a randomized, single-blinded (outcome assessors), parallel-group intervention hosted by "Hypertension Approaches in the Elderly: a Lifestyle study" multicenter, two-arm, randomized trial (HAEL Study). Participants who entered the HAEL Study in July 2019 or after were eligible. Randomization was generated by computer and allocation concealment by an independent investigator. The delivery of individual results was carried out in individual or group meetings between December 2019 and September 2020 at a Clinical Research Center. Outcomes were assessed by an unvalidated questionnaire on a 5-point Likert scale and multiple choice questions. **Results:** Of the 20 participants who agreed to participate in the SWAT, 10 from the individual format and 7 from the group format, with a mean age of 68 years old, were evaluated through per-protocol analysis. Most participants showed good understanding of their results in both delivery formats - individual 70% (7/10) and group 71% (5/7) (p=0.194). The satisfaction domain was well evaluated, and

the negative psychological impact was non-existent or very low. Any research-related physical harms were not identified. **Conclusion:** Both formats for delivering individual results generated adequate understanding and satisfaction with low negative emotional impact to a partial sample of older participants in the HAEL Study.

Register: Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT122). HAEL Study ClinicalTrials.gov (NCT03264443).

Keywords: research communication, dissemination of results, individual results, Patient and Public Involvement, Clinical Trial, SWAT.

Introduction

Communication is a pivotal process in clinical research. Notably, trial participants are stakeholders before, during and after an interventional study, which demands specific communication exchanges on pre-trial clarifications and proper guidance when they have engaged in the research. Therefore, communicating and disseminating aggregate or individual results to research participants has been considered as an ethical imperative, respecting their rights to know their own data and valuing their key role in the construction of scientific knowledge (1–5). Although there are guiding principles for returning individual research results (3,6), uncertainties still remain on format and contents to be disclosed (7,8).

Among potential barriers for improved trial dissemination for research participants, points of concern include insufficient budgetary planning, misinterpretation of findings, and possible negative emotional impact among participants (1,7,8). Nonetheless, the Patient and the Public Involvement (PPI) in the processes of planning, conducting and disseminating research (2,9–11) can minimize such barriers and facilitate participant-researcher communication, creating strategies that enable understanding data, potential uses and limitations (11–13). Additionally, positive impact is reported as the influence and empowerment decision-making regarding their own health, satisfaction with the study, and encouraging participation in future studies (1,11,14–16).

Surveys show that most participants (~90%) report an interest in knowing aggregated or individual data from the studies they participated in (4,15,17), albeit the practice of dissemination of such data is still uncommon among researchers (18–20). Only 27% of biomedical research clinical trial authors reported having disseminated the study results to

participants, while 13% planned to do so (20). Out of the 3381 respondents registered in a health research database, 33% reported receiving results from the studies in which they participated, whereas 52% had no opportunity to request their results (19). Furthermore, the research on individual results dissemination is mostly limited to genetic and cancer studies (4), and when it involves different clinical conditions or older population profiles are usually related to delivering aggregated results (4,12,15,16).

Older participants report preferences for receiving written and verbal health information (21) and research results in the format of a letter or face-to-face meetings (12,15,22). However, the implementation of these strategies for dissemination results is not clear in this population profile, so uncertainty as to the type of information, delivery format and communication style for dissemination individual results prevails. Importantly, there is a growing interest in more transparency in exercise sciences (23,24) and adequate tailoring of disclosure of results to participants could improve the perception of participants regarding the trial experience and physical activity engagement. Therefore, we conducted a study following the Study Within A Trial (SWAT) methods with the aim of evaluating two delivery formats of individual results to older participants of a physical activity program on the perspectives of understanding (main outcome), satisfaction, and short-term psychological impact. The present study was exploratory, with no directional hypothesis.

Methods

Study Design

The SWAT was framed as a randomized, single-blinded (outcome assessors), parallel group intervention hosted by “Hypertension Approaches in the Elderly: a Lifestyle study” multicenter, two-arm, randomized trial (HAEL Study) (NCT03264443), comparing the efficacy for blood pressure control by a combined exercise training program versus a health education program in older adults with hypertension, as described in the protocol (25). The study was registered on the Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT122) and its protocol is openly available at the Open Science Framework (OSF) (https://osf.io/cb6jx/).

Participants

For this SWAT, we invited all participants who entered the HAEL Study in July 2019 or after, and who had reached a minimum frequency of 25% in the intervention sessions of the host trial, which translates into 3 sessions in the health education program or 9 sessions in the combined exercise training program at the end of the 12 weeks.

Randomization and allocation concealment

The participants were allocated to delivering results in group or individual format based on computer-generated random numbers (random.org), with a 1:1 ratio, stratified by group on the host trial and with permuted blocks of random sizes. Allocation concealment was implemented by an independent investigator (DU) not involved with the intervention and data collection. Due to the nature of the interventions, neither the investigator who delivered the individual results nor the participants were blinded. Blinding was implemented for outcome assessors and data analysts of primary and secondary outcomes.

Setting

The data were collected at the Clinical Research Center/Hospital de Clínicas de Porto Alegre (Porto Alegre, RS, Brazil), from December 2019 to September 2020.

Ethics approval and consent to participate

The research was approved by the Ethics Committee for Research with Human Subjects of the Hospital de Clínicas de Porto Alegre (CAAE: 20688919.0.0000.5327). The procedures were guided by the Declaration of Helsinki and resolution no. 466/2012 of the National Health Council in Brazil. All patients provided written voluntary informed consent.

Interventions

The delivery of individual results to the participants of the HAEL Study was carried out either by an individual approach or group meetings. Both delivery approaches occurred in

person and were conducted by the same investigator (ATDN), graduated in Physical Therapy. In both delivery formats, a printed report was given to participants, displaying an initial welcome message followed by the individual results of blood chemistry, body composition, functional and strength performances, office blood pressure, cardiopulmonary exercise test, and ambulatory blood pressure monitoring associated with reference values available in the literature.

The individual format was carried out at a visit set to last up to 15 minutes. In this session, the investigator handed the report to the participant and read the results together with him/her, clarifying any doubts that arised.

The group-based format (one investigator with 3 to 4 participants) was carried out with the delivery of the printed report so that the participants could follow their information. This intervention was guided by the presentation of slides set to last up to 15 minutes. After explaining the standardized structure and displayed variables, the participants had another 15 minutes to ask questions and clear up their doubts, totaling up to 30 minutes of the visit. In comparison to the individual approach, this group visit was set to be longer due to possible interaction between participants based on individual and peer questions.

The standardized report is openly available at the study materials repository (Supplementary file 1 - https://osf.io/5kdqg/).

Measures and outcomes

The SWAT participants initially answered a non-validated self-administered questionnaire with 7 questions on sociodemographic characteristics and 3 opens questions regarding expectations upon receiving the results. Afterwards, the Montreal Cognitive Assessment (MoCA) test was applied to assess mild cognitive impairment (26). This tool consists of 11 questions measuring cognitive domains through several tasks: short-term memory (delayed recall), visuospatial abilities (clock-drawing task and a three-dimensional cube copy), executive functions (trail-making test, phonemic verbal fluency, verbal abstraction), attention, concentration and working memory (sustained attention task, a serial subtraction task, and digits forward), language (nomination, sentence repetition), and orientation to time and space. The application time is approximately 10 to 15 minutes, and the test final score was determined by the sum of different cognitive domains. The score range

varies from 0 to 30, whereas a final score of 26 or higher is considered as “normal”, the scores of 25 or below are considered to be indicative of possible “mild cognitive impairment”. To counterbalance the effect of lower educational levels, 1 point was added to the final score of those individuals with ≤ 12 years of education (26). This instrument was used as a control variable for possible confounding on the main outcome. The application was conducted by a physiotherapist trained and certified in MoCA administration (ATDN), and the score analyzed together with a second researcher.

The assessment of report understanding, satisfaction with dissemination format, and short-term psychological impact outcomes was performed using a non-validated self-administered questionnaire, which was based on previous questionnaires (11,12,16,19,27,28). This questionnaire included 14 items in 5-point Likert scale and additional 6 multiple choice questions that were applied to assess the understanding of data after the intervention as well as comparison of some results (e.g., cholesterol levels) in relation to reference values (Supplementary file 2 - https://osf.io/qykmp/).

Primary outcome

The prespecified primary outcome in this study was the performance in the five multiple-choice (single answer) questions measuring participants' understanding in relation to their own data. The items of questionnaire considered for evaluation of the understanding domain were related to the following variables: (i) cholesterol; (ii) body mass index; (iii) functional tests battery; (iv) blood pressure; (v) cardiorespiratory capacity. We considered it as an “adequate understanding” when the participant achieved four to five questions answered correctly, whereas zero to three questions answered correctly were considered as “inadequate understanding”.

Secondary outcome

The domains related to the satisfaction with results delivery and psychological impact were assessed using Likert scale questions. The satisfaction was assessed considering: (i) object; (ii) quality; and (iv) effect of delivery (questions 2 to 9). Psychological impact was assessed considering: (i) level of concern; (ii) level of anxiety; (iii) fearful feelings; and (iv) feelings of sadness (questions 12 to 15).

Three remaining items (questions 10, 11 and 19) of the questionnaire were analyzed separately and not within the domains. These questions were related to the recommendation to participate in studies such as the HAEL Study, general self-assessed understanding of the individual report, and interpretation of blood pressure values after the trial. We did not consider the sum of these questions in the comprehension domain, as they did not show leveling of response options, which led to a subjective analysis by the participants about values considered adequate for blood pressure.

Sample size

The SWAT was conceived during the HAEL Study, therefore no formal sample size calculation was performed, which is in line with SWAT methodology (29). Thus, from the sample calculation of the host trial of 184 participants, we counted that 50 participants needed to be recruited to complete the sample and receive the individual results, this being the estimated sample for entry into the SWAT. The projected sample size was not reached mostly because there was an early closure of the HAEL Study due to the COVID-19 pandemic.

Statistical analyses

This was a mixed methods study, using a qualitative and quantitative approach. Data were analysed using descriptive and inferential statistics. The normality of the data distribution was assessed using the Shapiro Wilk test. The difference between delivery formats and understanding was assessed using Fisher's exact test. Spearman's correlation was used to examine the association between the level of understanding and the MoCA instrument, and the association between the level of education and the MoCA was verified by Pearson Chi-Square. Continuous data are presented as mean ± standard deviation and categorical data as absolute and relative frequencies. The analyses were performed per protocol using the PASW Statistics for Windows software (Version 18.0 Chicago: SPSS Inc). The level of significance was set at 5%.

Changes to the planned protocol

Some protocol changes should be mentioned. First, we planned the group format meeting to take place with 4 to 6 participants. However, due to necessary schedule arrangements, most group meetings occurred with 3 to 4 participants (as described in the intervention item). Second, given the context of the pandemic, the delivery of results from 3 participants who were allocated to receive in group format was modified for individual delivery. Third, our data analysis plan was modified. In evaluating the understanding domain outcome, we modified the score analysis that ranged from 0 to 5 points. To make the score more readily interpretable, we simply inverted the numerical scale of a given individual result, displaying a score of lower scores (zero to three) as an “inadequate understanding”, and increasing score (up to 5) as a more adequate understanding. In addition, changes were made to the statistical tests due to the small sample size, the low frequency of responses made it impossible to carry out the tests suggested a priori.

Results

Of the 50 participants estimated to enter the host trial from July 2019, only 33 participants entered and 24 completed the activities before lockdown due to the COVID-19 pandemic. Of these, 20 agreed to participate in the SWAT (Figure 1). Two meetings were held for group delivery, both planned with 4 participants, however, one of them did not show up, which resulted in 3 participants for one of the group deliveries. Also, following the per-protocol analysis, the data from 3 participants who had the format of delivery of the results changed were excluded, and we considered only data from 17 participants.

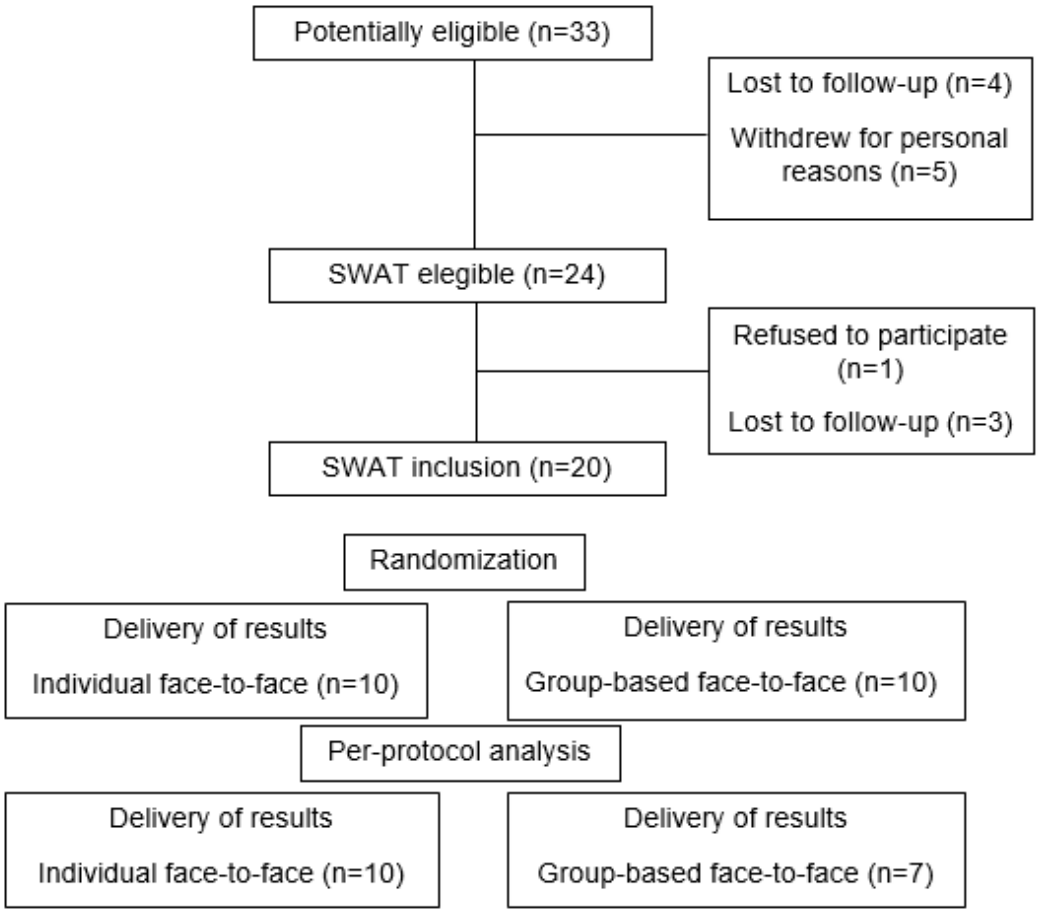

Figure 1. Flowchart SWAT

The characteristics of the participants are shown in table 1. The average age was 68 years (range 60-79 years), with the majority being women (11/17, 64.7%). The educational level from complete high school was reported by 7 (41.3%) participants. Approximately 29% of participants reached a score of ≥ 26 points in MoCA test; years of education were not associated with the MoCA final score (p=0.372).

Table 1. Characteristics of SWAT participants

	All (n=17)	Individual face-to-face (n=10)	Group-based face-to-face (n=7)
Sex			
Male	6 (35.3)	5 (50)	1 (14.3)
Female	11(64.7)	5 (50)	6 (85.7)
Age (years)	67.7 ± 5.5	68.6 ± 5.8	68 ± 4.8
Ethnicity (self-reported)			
White	12 (70.6)	6 (60)	6 (85.7)
Black	4 (23.5)	3 (30)	1 (14.3)
Other	1 (5.9)	1(10)	-
Educational level			
Incomplete elementary school	1 (5.9)	-	1 (14.3)
Complete elementary school	5 (29.4)	2 (20)	3 (42.9)
Incomplete high school	4 (23.5)	2 (20)	2 (28.6)
Complete high school	2 (11.8)	2 (20)	-
Incomplete graduate degree	2 (11.8)	2 (20)	-
Complete graduate degree	2 (11.8)	1 (10)	1 (14.3)
Postgraduate	1 (5.9)	1 (10)	-

Internet at home	13 (76.5)	7 (70)	6 (85.7)
MoCA Test (score total ≥26 points)	5 (29.4)	4 (40)	1 (14.3)
Source group HAEL Study			
Combined exercise training	10 (58.8)	6 (60)	4 (57.1)
Health education	7 (41.2)	4 (40)	3 (42.9)

Description: Values expressed as mean ± SD and n (%)

In the pre-intervention questionnaire, most participants (15/17) expected to receive all their results after the study, and when asked what they expected to understand from the information made available, most reported (12/17) "knowing about my conditions and health status". However, we highlight some answers that varied, such as: "depending on the results, make a change in the routine, in food, get out of a sedentary lifestyle to improve the quality of life"; “I hope to understand if I need to seek medical attention”; “I hope to have a better understanding of what physical exercise has provided to improve my health”; “General orientation for health and mainly to improve memory”, and “How to take better care of myself and my health”.

Regarding the participants' understanding of their own data reported in the printed document, the majority of participants reaching an adequate understanding (4 to 5 correct answers, out of five). The proportion was quite comparable between individual (7/10; 70%) and group dissemination formats (5/7; 71%), with no statistical difference detected between delivery formats (Table 2). There was no correlation between the MoCA test and the participants' understanding ($r = 0.284$; $p = 0.269$).

In general, participants reported understanding the results that were presented to them (question 11). Of these, a total of 6 individuals indicated “I understood a lot” of which 4 received their report in the individual format and 2 in the group format. The other participants chose the option “I understood”. Regarding the participants' perception of their office blood pressure values after interventions in the HAEL Study, 15 participants considered their values as “good”, data ranging between 105/68 mmHg and 143/88 mmHg. Only one participant (from the group

format) indicated to be “indifferent” to the blood pressure values (104/81 mmHg) and one (from the individual format) judged the values as “bad” (147/89 mmHg).

Table 2. Understanding domain

	Individual face-to-face (n=10)	Group-based face-to-face (n=7)	p-value
Understanding			
(2-3 correct answers)	3 (30.0)	2 (28.6)	
(4-5 correct answers)	7 (70.0)	5 (71.4)	0.194

Description: Values expressed as n (%)

In the satisfaction domain, the items related to the adequateness in receiving research results were mostly considered as “very adequate”/ “adequate” and “very interesting”/ “interesting”, with only two people (from the group format) answering that they were indifferent to receiving the results. In items related to the quality of delivery, participants reported adequate clarity and satisfaction without the need for further clarification by the study team. The items that assessed the effects of delivery were the ones that most oscillated between the responses, but all participants indicated “a lot of influence”/“influence” when knowing their results with greater health care, regardless of the dissemination format (Table 3). We observed that of the 12 participants who mentioned some level of need (“little needed”, “needed” and “very needed”) to investigate further information about their health with their doctor or health care professional, ten participants had an adequate understanding of their results (4 to 5 correct answers), however, nine participants presented a mild cognitive impairment score. In relation to potentially endorsing participation in trials similar to the HAEL Study, most participants (13/17) mentioned that they "definitely would recommend".

Table 3. Satisfaction delivery of results

Satisfaction domain	Individual face-to-face (n=10)	Group-based face-to-face (n=7)
Delivery object		
1 Do you consider it appropriate to receive the individual results of the study?		
Very adequate	5 (50)	3 (42.9)
Adequate	5 (50)	2 (28.6)
Indifferent	-	2 (28.6)
Not adequate	-	-
Nothing adequate	-	-
2 Do you think the results presented are interesting?		
Very interesting	9 (90)	4 (57.1)
Interesting	1 (10)	3 (42.9)
Indifferent	-	-
Not very interesting	-	-
Nothing interesting	-	-
Delivery quality		
3 Did you find the description of the individual results presented clear?		
Very clear	8 (80)	3 (42.9)
Clear	2 (20)	4 (57.1)
Indifferent	-	-
Unclear	-	-
Nothing clear	-	-

4 How do you rate your satisfaction with the method used to receive the results?		
Very satisfied	4 (40)	3 (42.9)
Satisfied	6 (60)	4 (57.1)
Indifferent	-	-
Not very satisfied	-	-
Not at all satisfied	-	-
5 Is there any need for further clarification from the study team on its results?		
Nothing needed	6 (60)	6 (85.7)
Little needed	3 (20)	1 (14.3)
Indifferent	1 (10)	-
Needed	-	-
Very needed	-	-
Delivery effect		
6 How do you rate the influence of knowing your results with greater health care?		
Very influence	8 (80)	6 (85.7)
Influence	2 (20)	1 (14.3)
Indifferent	-	-
Little influence	-	-
No influence	-	-

7 Do you think it is necessary to discuss or investigate more about this information with your doctor or health care professional?		
Nothing needed	4 (40)	-
Little needed	1 (10)	2 (28.6)
Indifferent	1 (10)	-
Needed	3 (30)	4 (57.1)
Very needed	1 (10)	1 (14.3)
8 Would you be more likely to participate in a clinical trial if you knew you would receive your results at the end of the study?		
Definitely yes	2 (20)	-
Probably yes	4 (40)	4 (57.1)
Do not know	1 (10)	1 (14.3)
Probably not	1 (10)	1 (14.3)
Definitely not	2 (20)	1 (14.3)

Description: Values expressed as n (%)

In the short-term psychological impact domain, states of anxiety, fear, and sadness when knowing their own data were non-existent or very low among most participants in both delivery formats. However, the state of concern showed more variable results, reported by 4 participants in the individual format and 3 in the group format (Table 4). The same participants who mentioned concern when knowing about their data also reported some level of anxiety ("very anxious"/ "anxious" or "little anxious"), and only one of these participants showed an inadequate understanding of their data (2 correct answers).

Table 4. Psychological impact domain

	Individual face-to-face (n=10)	Group-based face-to-face (n=7)
Concerned		
Nothing concerned	6 (60)	3 (42.9)
Little concerned	-	1 (14.3)
Indifferent	-	-
Concerned	4 (40)	3 (42.9)
Very concerned	-	-
Anxiety		
Nothing anxious	4 (40)	2 (28.6)
Little anxious	2 (20)	2 (28.6)
Indifferent	-	1 (14.3)
Anxious	2 (20)	1 (14.3)
Very anxious	2 (20)	1 (14.3)
Fear		
Nothing of fear	6 (60)	3 (42.9)
Little fear	3 (30)	2 (28.6)
Indifferent	-	1 (14.3)
Fear	1 (10)	1 (14.3)
Very fear	-	-
Sadness		
Nothing sad	9 (90)	4 (57.1)
Little sad	1 (10)	-
Indifferent	-	3 (42.9)
Sad	-	-
Very sad	-	-

Description: Values expressed as n (%)

Harms

We did not identify any research-related physical harms or psychological discomfort, in addition to the outcomes assessed in the study.

Discussion

This SWAT identified that both delivery formats of individual results to older participants in the HAEL Study generated adequate understanding, satisfaction and low negative emotional impact. Our findings corroborate studies that evaluated the older participants' perspectives on satisfaction (16) and understanding (12) when receiving aggregated results of the study. Although there are recommendations and guides that mention the right of participants to receive their data and encourage researchers to disseminate aggregated and individual results (3,6,30), to our knowledge, this study is the pioneer in assessing the delivery of individual results in the physical activity field.

The concern with the misinterpretation of results is identified as a barrier to dissemination, as well as possible emotional burden (1,4,8), which leads researchers to mention that the results should not always be shared with participants (8). The decreased sensory-perspective capacities of the aging process, which affect the ability to receive and treat information from the environment (31,32), can also be considered a concern to dissemination of results to older participants together with the condition of arterial hypertension that contributes to cognitive decline (33,34). However, we observed that most participants (12/17) with scores for mild cognitive impairment (below 25 points in the MoCA Test) (26) showed good understanding (4 and 5 correct answers). The use of simple language, explanations about sharing numerical data and visual strategies are recommended to ensure understanding among participants and may have contributed to our findings (22,30). Moreover, we emphasize that the interpretation of a score below the cutoff point considered as “normal” in the MoCA does not necessarily have a direct impact on cognitive function, since factors such as stress, fatigue, emotional state, and educational level may influence the test performance (26,35).

We underscore that the dissemination of the individual results is a right and desire expressed by research participants (4,12) even when it offers a possible risk of emotional

impact (4,36). As observed in our data, the majority of participants (15/17) considered “adequate” or “very adequate” to receive the individual results of the study, and all reported as "interesting" and "very interesting" the data presented in their reports. In addition, knowing about their own results generated “Much influence”/ “Influence” with greater health care, and interest in investigating or discussing more with a health professional. These findings reflect satisfaction with the delivery object and related effects, facilitating further actions to health promotion in trial participants (1,4).

Together with the participant’s interest, understanding and satisfaction in receiving research results, the potential physical and emotional impact should be considered. We reason that most trials with physical activity interventions would present some outcomes highly valuable to be known by participants, with low odds for generating exaggerated states of concern.

In addition, involving participants more actively in the planning of results delivery may enable clear and effective communication between participants and researchers, reducing possible barriers to dissemination and empowering the participants for decision-making in health (3,9,10,28).

Strengths and Limitations

This SWAT provides important information about the dissemination of individual results to older participants, however, some limitations should be considered. First, although the outcomes of understanding, satisfaction and psychological impact were comparable in the two delivery formats, the small sample size in our study likely reduces the generalization of findings. Second, the questionnaire developed to assess the outcomes of interest contemplated few questions and was not validated, which may impair the reliability of the findings. However, as we did not identify questionnaires for individual results delivery in the literature, we refer to articles that evaluated the aggregated results delivery and we refined and organized the questions into domains, which can contribute to future validation studies. Third, SWAT participants were older adults with hypertension. Thus, the layout, format, and language of the results delivery were based on information from the literature for this population profile, which limits generalization to other target audiences. Fourth, the involvement of participants in the construction of different delivery formats was not considered since the initial phase, which

could have identified other preferences to dissemination as email, text message or video. Despite these limitations, the study findings do support the importance of returning participants' results and exercising the participant-centered communication. This study is an initial but important step to encourage further research and practices aimed at greater transparency and accountability to trial participants, especially with a focus on effective and clear communication for older subjects or those with potential difficulties in understanding their data.

Conclusion

Older participants showed adequate understanding and satisfaction in both formats for delivering individual results face-to-face meetings, in addition to low negative emotional impact. From this study we suggest further SWAT research on the dissemination of individual results, evaluating the preference of different delivery formats based on the involvement of the patient and the public through focus groups.

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

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Data sharing

Data from this study will be shared in the Open Science Framework (https://osf.io/d4mfs/).

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Supplementary file 1. Delivery model of the printed document for the dissemination of individual results to the participants.

Individual Results from the HAEL Study

Project:

Perspectives of participants in a clinical trial with hypertensive older people on the return of individual results: study within a trial (SWAT)

Initial message

Dear,

A fundamental part of scientific studies is the return of results to research participants.

In this document, we will present your information from the exams and assessments carried out during your participation in the study “Combined physical training and health education for elderly people with arterial hypertension: a randomized, multicenter clinical trial” (HAEL Study).

The HAEL study compared two interventions aimed at the health of people with high blood pressure; one of the interventions was a physical exercise program, and the other was a health education group.

We thank you, once again, for the possibility of interaction and your important support for our work.

Organization of this report

The data presented below are divided into four parts, which are:

- Body composition
- Blood tests
- Blood pressure
- Functional tests

Their results refer to the moments before and after the period of their participation in the HAEL study. The dates for the beginning of your initial and final assessments are shown below:

Evaluation start date - **before the intervention starts:**

Start date of the evaluations - **after the end of the intervention:**

Body composition

The results below refer to your body measurements assessed using a scale and measuring tape. The body mass index (BMI) is calculated using the ratio of your body weight and your height.

Your height:

Variable	Before	After
Weight (kg)		
Waist circumference (cm)		
*Total body mass index (kg/m²)		

Body Mass Index Classification

Low weight	**Suitable weight**	**Overweight**
Less than 22 kg/m2	Between 22 and 27 kg/m2	Equal or greater than 27 kg/m2

Ministério da Saúde, BRASIL

Blood tests

The results of your blood tests correspond to the collection carried out on the 1st floor of the Clinical Research Center, by a specialized professional.

The reference values are based on the Laboratory Diagnostic Service of the Hospital de Clínicas de Porto Alegre, except for the glucose control values that are based on the Brazilian Diabetes Directive.

Variable	Before	After	Reference values

Total cholesterol (mg/dL)			Low risk: < 200 mg/dL Moderate risk: 200 a 239 mg/dL High risk: = or > 240 mg/dL
HDL Cholesterol (mg/dL)			Low risk: > 60 mg/dL Moderate risk: 35 a 60 mg/dL High risk: < 35 mg/dL
LDL Cholesterol (mg/dL)			Low risk: < 100 mg/dL Desirable: 100 a 129 mg/dL Limit: 130 - 159 mg/dL High: 160 - 189 mg/dL Very high: ≥190 mg/dL
Triglycerides (mg/dL)			Great: < 150 mg/dL Limit: 150 - 200 mg/dL High: 201 - 499 mg/dL Very high: = or > 500 mg/dL
Creatinine (mg/dL)			Women: 0.50 – 0.90 mg/dL Men: 0.70 – 1.20 mg/dL
Glycated hemoglobin (HbA1c %)			Normal < 5.7 Prediabetes: 5.7% - 6.4% Diabetes: ≥ 6.5%

Blood pressure

The values below represent the main result of our study.

Office blood pressure corresponds to the average of three measurements of your blood pressure (BP) performed in the laboratory.

The 24-hour BP, performed by the Ambulatory Blood Pressure Monitoring (ABPM) exam, corresponds to your systolic and diastolic blood pressure during the time bands from 6:00 am to 10:00 pm - day period, and from 10: 00 pm to 6:00 am - night time.

Variable	Before	After
Office BP (mmHg)		
24-hour BP (mmHg) During day (mean)		
24-hour BP (mmHg) During sleep / night (mean)		

Functional tests

The functional tests described below are considered markers of their functional state.

Hand grip (hand tightening) indicates the highest strength achieved in the three attempts with each arm.

The physical performance battery is made up of three assessments that you performed: balance tests, gait speed (walking) and test to get up from the chair.

The cardiopulmonary stress test corresponds to your walking or running test on the treadmill. The values indicate cardiorespiratory fitness, which is an important health marker.

Variable	Before	After
Hand Grip Dominant Hand		
Hand Grip Non-dominant hand		
Physical performance battery		

Maximum volume of oxygen - VO2 Max. (ml/kg/min)		
Maximum heart rate (bpm)		
1 minute Blood pressure (mmHg)		
Test time		

Reference values (Women):

Hand Grip (mean in Kilogram force-kgf):

Right hand:	**Left hand:**
60-64 years: 24.99 Kgf	60-64 years: 20.73 Kgf
65-69 years: 22.49 Kgf	65-69 years: 18.60 Kgf
70-74 years: 22.49 Kgf	70-74 years: 18.82 Kgf
75 years or older: 19.32 Kgf	75 years or older: 17.05 Kgf

Maximum oxygen consumption (VO2 max) (ml/kg/min):

60-69 years:	**70-79 years:**	**80 years or older:**
<15.95 = Very weak	<14.18 = Very weak	<13.97 = Very weak
15.96 -18.13 = Weak	14.19 – 15.95 = Weak	13.98 – 15.87 = Weak
18.14 – 20.04 = Regular	15.96 – 17.78 = Regular	15.88 – 17.25 = Regular
20.05 – 22.29 = Good	17.79 – 20.90 = Good	17.26 – 19.11 = Good
>22.29 = Great	>20.90 = Great	>19.11 = Great

Reference values (Men):

Hand Grip (mean in Kilogram force-kgf):

Right hand:	**Left hand:**
60-64 years: 40.68 Kgf	60-64 years: 34.83 Kgf
65-69 years: 41.32 Kgf	65-69 years: 34.83 Kgf
70-74 years: 34.15 Kgf	70-74 years: 29.39 Kgf
75 years or older: 29.8 Kgf	75 years or older: 24.94 Kgf

Maximum oxygen consumption (VO2 max) (ml/kg/min):

60-69 years:	**70-79 years:**	**80 years or older:**
< 20.61 = Very weak	<18.26 = Very weak	< 16.11= Very weak
20.62 – 23.79 = Weak	18.26 – 20.64 = Weak	16.12 – 17.20 = Weak
23.80 – 27.08 = Regular	20.65 – 22.22 = Regular	17.21 – 19.04 = Regular
27.09 – 31.00 = Good	22.23 – 25.64 = Good	19.05 – 22.76 = Good
>31.00 = Great	>25.64 = Great	>22.76 = Great

Physical performance battery:

The score ranges from 0 to 12, generating the following classification according to the score: 0 to 3 points: disability or poor capacity;

4 to 6 points: low capacity;

7 to 9 points: moderate capacity;

10 to 12 points: good capacity

Attachments

The documents below refer to more detailed data from your Cardiopulmonary Stress Test and Ambulatory Blood Pressure Monitoring (ABPM):

 **Cardiopulmonary Test**

Before (date)

mL.Kg-1.min-1 % of predicted

Resting electrocardiogram

Rhythm

Conduction

ST Segment

Heart rate (HR) response:

HR pre-effort (bpm):

Peak HR (bpm):

HR (% predicted):

Blood pressure (BP) response:

Pre BP (mmHg): Peak BP (mmHg):

HR recovery in the first minute (bpm) =

After (date)

mL.Kg-1.min-1 % of predicted

Resting electrocardiogram

Rhythm

Conduction

ST Segment

Heart rate (HR) response:
HR pre-effort (bpm):
Peak HR (bpm):
HR (% predicted):

Blood pressure (BP) response:

Pre BP (mmHg): Peak BP (mmHg):

HR recovery in the first minute (bpm) =

Supplementary file 2. Questionnaire for assessment of outcomes understanding, satisfaction and short-term psychological impact

Post-intervention questionnaire

Date: ___/___/___ ID:_____

The following questionnaire was designed to verify your understanding of the information received from the individual results, the satisfaction of the format used for the dissemination of these results and the psychological impact when receiving them.

There are no right or wrong answers, we are interested in your opinion. If you are unsure how to respond, please choose the answer that best suits you.

After completing the questionnaire, we request that you return it to the researcher. Any information you provide will be considered strictly confidential.

We appreciate your availability when answering the questionnaire and inform you that as soon as the study is completed, the general results of the study will be posted on the HAEL website (https://www.ufrgs.br/hael).

1. Which of the formats for disclosing individual results did you participate?

( ) Individual face-to-face dissemination format

( ) Group-based face-to-face dissemination format

When answering the following questions, please circle only one number.

2. Do you consider it appropriate to receive the individual results of the study?	Very adequate (5)	Adequate (4)	Indifferent (3)	Little adequate (2)	Nothing adequate (1)

3. Did you find the description of the individual results presented clear?	Very clear (5)	Clear (4)	Indifferent (3)	Little clear (2)	Nothing clear (1)
4. Do you think the results presented are interesting?	Very interesting (5)	Interesting (4)	Indifferent (3)	Little interesting (2)	Nothing interesting (1)
5. How do you rate the your satisfaction with the method used to receive the results?	Very satisfied (5)	Satisfied (4)	Indifferent (3)	Not very satisfied (2)	Not at all satisfied (1)
6. Knowing your individual results can influence greater care for your health. How do you rate the influence of knowing your results with greater health care?	Very influence (5)	Influence (4)	Indifferent (3)	Little influence (2)	No influence (1)
7. Is there any need for further clarification from the study team on its results?	Nothing needed (5)	Little needed (4)	Indifferent (3)	Needed (2)	Very needed (1)

8. After being aware of your research results, do you think it is necessary to discuss or investigate more about this information with your doctor or any healthcare professional?	Nothing needed (5)	Little needed (4)	Indifferent (3)	Needed (2)	Very needed (1)
9. Would you be more likely to participate in a clinical trial if you knew you would receive your results at the end of the study?	Definitely yes (5)	Probably yes (4)	I do not know (3)	Probably not (2)	Definitely not (1)
10. Would you recommend other people to participate in a study like HAEL?	Definitely yes (5)	Probably yes (4)	I do not know (3)	Probably not (2)	Definitely not (1)
11. How do you rate your understanding of your presented results?	I understood a lot (5)	I understood (4)	Indifferent (3)	I understood little (2)	I did not understand (1)
12. How do you rate your level of concern when you know about your results?	Very concerned (5)	Concerned (4)	Indifferent (3)	Little concerned (2)	Nothing concerned (1)

13. How do you rate your anxiety level when you are aware of your results?	Very anxious (5)	Anxious (4)	Indifferent (3)	Little anxious (2)	Nothing anxious (1)
14. Did you feel scared to know your individual results?	Very fear (5)	Fear (4)	Indifferent (3)	Little fear (2)	Nothing fear (1)
15. Did you feel sad to know your individual results?	Very sad (5)	Sad (4)	Indifferent (3)	Little sad (2)	Nothing sad (1)

Checking your results sheet, answer the following questions:

16. From the statements below, which one do you think best describes the result of your LDL cholesterol test after the HAEL study intervention? Check only one option.

( ) My LDL results after participating in the HAEL Study are within or below desirable reference values.

( ) My LDL results after participating in the HAEL Study are above the desirable reference values.

( ) Do not know.

17. When comparing the values before and after your body mass index (BMI), which statement do you think best describes your results? Check only one option.

( ) Comparison of the values indicated a decrease in my body mass index.

( ) Comparison of the values indicated an increase in my body mass index.

( ) There was no difference when comparing the values of my body mass index pre and post.

18. Considering that the functional test battery (balance tests, gait speed and standing up test) assesses the function of the lower limbs, and that the sum of each item generates a total score of 0 to 12 points (0 being worst performance and 12 the best). Which of the options below best describes your results in the period after your participation? Check only one option.

( ) 0 to 3 points - disability or very poor performance.

( ) 4 to 6 points - low performance.

( ) 7 to 9 points - moderate performance.

( ) 10 to 12 points - good performance.

19. When analyzing your office blood pressure value, after participating in the study, which of the information below do you consider best to describe your results? Check only one option.

( ) I consider the value of my office blood pressure to be good.

( ) I consider the value of my office blood pressure to be bad.

( ) Indifferent.

20. According to your knowledge, blood pressure values of 150/90 mmHg, that is, 15 by 9 mmHg are considered:

( ) Low value for blood pressure.

( ) High value for blood pressure.

( ) Normal value for blood pressure.

21. The treadmill test or Cardiopulmonary Stress test, which you performed in the period before and after the HAEL study interventions, reports values of the maximum volume of oxygen (VO2 max) that your body consumes during physical exercise, being considered a sign of your physical condition. Therefore, comparing the values you reached before and after the intervention, you would say that:

( ) My physical conditioning has increased.

( ) My physical conditioning has decreased.

( ) My physical conditioning has not changed.

6. ARTIGO 2

Quality of reporting in abstracts of randomized clinical trials of physical activity: a cross-sectional study using the CONSORT for Abstracts

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Abstract

Aim: to investigate the quality of reporting in abstracts of randomized clinical trials (RCTs) in the physical activity field, according to adherence to the Consolidated Standards of Reporting Trials (CONSORT) for Abstracts (primary outcome), and to analyze the recommendations of the selected journals regarding the contents and structure of the abstract. **Methods:** This descriptive study is characterized as an extension of the Strengthening the Evidence in Exercise Sciences (SEES) Initiative, which uses a methodological design of meta-research. Eligible RCTs assessed by the SEES during the year 2019, published in 11 general medicine and exercise sciences journals, and that had, at least, one intervention arm based on physical activity counseling or an exercise intervention program. Two researchers independently

assessed the items included in the CONSORT for Abstracts and checked each journal's instructions to authors in relation to the abstracts session. **Results:** 131 RCTs were selected for evaluation in the present study. Only five articles were published in general medicine journals and 126 were published in exercise sciences journals. Of the 16 items evaluated by CONSORT for Abstracts, the items that presented the best report were objectives or hypothesis (99.2%), intervention (93.9%) and conclusion (98.4%), low reporting was observed mainly in allocation and randomization (1.5%), number of participants analyzed (6.1%) and funding (0.8%). Ten journals recommend the abstract structure, but only two endorse the CONSORT for Abstracts. **Conclusion:** There is variable and suboptimal adherence to the CONSORT for articles abstracts checklist in the physical activity field, and poor recommendation of this instrument of pre-selected and evaluated journals in the year 2019. Based on this study, we called the attention of editors, reviewers, and authors to consider strict adherence to CONSORT for Abstracts, in order to promote transparency, integrity, and quality in the dissemination and communication of clinical trials in the physical exercise field.

Introduction

Abstracts are highly important sections in the publication of scientific articles. Besides being the only part of the article with easy access indexed in electronic databases, abstracts provide key study information and is usually the most read section from biomedical publications (1,2). Thus, the information included in the abstract is likely to influence the assessment of the study and the applicability of the findings (1–3). Therefore, specific and clear information is important and should be prioritized in abstracts, especially of randomized clinical trials (RCTs), which are considered the gold standard design for the assessment of therapeutic-preventive interventions (2,4,5).

Since 2008, a CONSORT extension provides reporting standards for RCTs' abstracts in journals or conferences. This extension describes a minimum list of essential items which should be considered for good quality of reporting in abstracts, with clear dissemination and communication of the different stages of the study and their results (2). However, despite these recommendations, studies have identified that the quality of reporting of abstracts in health sciences is still suboptimal (6–10). Inconsistencies and non-adherence to the recommended

items are mainly identified in methodological quality domains (3). Furthermore, there is low mention of the CONSORT for Abstracts (7%, 11/168) in “Instructions for Authors” sections from most journals compared to the full CONSORT guideline (11), which can reflect in a low-quality reporting by the authors of the studies.

A systematic review with meta-analysis synthesized the evidence from studies that compared the quality of reporting in RCTs abstracts of different health areas, before and after the publication of the CONSORT for Abstracts (10). Out of 10 studies included, with an analysis of 5184 abstracts, nine concluded that adherence to the CONSORT for abstracts was poor, suboptimal, or inadequate, and one of the studies concluded that active implementation of the guideline can lead to improvements in quality of reporting. The authors also identified that items of CONSORT for Abstracts were subdivided in some assessments, with no standardization between the studies (10).

The quality of reporting based on CONSORT for Abstracts has not been addressed in the RCTs’ of physical activity interventions. However, such interventions are essential for the prevention and treatment of several health conditions (12,13), and inadequate or incomplete reporting may compromise the decision-making by stakeholders or, at least, misinform potential readers. In this way, the present study aimed to summarize the quality of reporting in abstracts of RCTs of physical activity, according to adherence to the CONSORT for abstracts (primary outcome), and to analyze the recommendations to authors of the selected journals regarding the contents and structure of the abstract. This analysis was based on the RCTs of physical activity included in the 2019 annual assessment of the “Strengthening the Evidence in Exercise Sciences” Initiative (SEES Initiative).

Methods

Design

This descriptive cross-sectional study derives from the SEES Initiative, which is an ongoing collaborative nonprofit project for the surveillance of published research in the exercise sciences (RCTs and systematic reviews with meta-analysis) and dissemination of practices and recommendations for integrity and transparency in research (www.sees-initiative.org). The SEES Initiative methodological design relates to a meta-research

prospective approach, mostly regarding post-publication analyses, and, therefore, submission to ethics committees was not applicable to this study. The project was launched in January 2019, with a protocol available in the Open Science Framework repository (OSF) (https://osf.io/2cu8g/). The present study does not present a protocol.

Organization and Literature search

The SEES Initiative is operated by trained researchers organized in different committees. The pre-evaluation committee conducts the search and selection of articles in the literature. The evaluation committee carries out the evaluation of the eligibility criteria and conducts the extraction of data according to the items on the form. The post-evaluation committee is responsible for the management and dissemination of data.

The literature search was conducted in PubMed/MEDLINE between the 3rd to 7th day of each month of 2019. The search strategy for the recovery of clinical trials followed an established filter of high sensitivity by Robinson and Dickersin (14). In addition, a date filter was added restricting searches from the previous two months, ie, each month was queried twice. For example, February was included in the survey conducted in both March and April. The choice for this procedure resulted from the variability of reference indexing time, thus enabling a reduction in the loss of some references.

Eligibility criteria

We included the RCTs assessed by the SEES Initiative from January to December 2019, published in 11 journals categorized by Web of Science, 9 journals of exercise science/sports medicine (American Journal of Sports Medicine, British Journal of Sports Medicine, European Journal of Preventive Cardiology, International Journal of Behavioral Nutrition and Physical Activity, Journal of Physiotherapy, Journal of Science and Medicine in Sport, Medicine, and Science in Sports and Exercise, Scandinavian Journal of Medicine & Science in Sports and Sports Medicine) and 2 journals of general medicine (British Medical Journal, Journal of the American Medical Association). The included studies had to have at least one intervention arm based on physical activity counseling or an exercise intervention program. Studies with multifaceted interventions (e.g., comprehensive lifestyle intervention or

health education program) were also included. Articles that did not include an electronic abstract were excluded.

We only considered data from 2019 due to the greater representation of the SEES Initiative proposal and the consistency of the analyses.

Screening

Two trained researchers (ATD and LMG, physiotherapist and physical educator, respectively), members of the evaluation committee for RCTs of SEES Initiative, independently assessed the items included in the CONSORT for Abstracts and checked each journal's instructions to authors in relation to the abstracts session. The researchers first piloted the data extraction form to ensure consistency in the extraction process. Discrepancies between authors on the application of checklist items were resolved by consulting the published explanation of the CONSORT for Abstracts and by examples provided (2), and when necessary by a third reviewer (DU).

Data extraction

We prepared two forms to respectively collect (1) the recommendations of the journals on contents and structure of the abstract, and (2) the adherence of the articles to the items recommended by the CONSORT for Abstracts. Both forms were completed independently by two researchers (ATD and LMG). The form for the journal's recommendations was built on the basis of commonly available instructions to authors. The second form included 16 recommended CONSORT items for Abstracts in journals (Supplementary File 1). The checklist item named "authors", which corresponds to the corresponding author's contact details was not counted in this assessment as it is considered a specific item for conference abstracts (2).

The extraction of the "recruitment" item n was based on the available abstracts model, which considered this item with information about the follow-up period of trial. The description of the "conclusion" item in CONSORT for Abstracts mentions benefits and harms of interventions, however, we did not use this content in our evaluation. Instead, we chose a more

parsimonious approach, following the abstract examples provided in the guidelines and considering as "yes" the abstracts that consistently presented the overall results. Likewise, in the trial registration item, adherence is recommended when there is a registration number and name of the trial register, however, we scored as “adherent” when at least one of these pieces of information was made available. This item was assessed based on the information displayed on the first page of the article, that is, on the abstract page.

Analyses

The descriptive analyses of the data was performed using the PASW Statistics for Windows software (Version 18.0 Chicago: SPSS Inc). Data are presented in absolute frequency (n) and percentages according to adherence to the items that received each possible answer.

The items in most forms have a binary response option (yes/no), which “yes” indicates adherence to the recommended practice. For three items (participants, randomization, and results of the primary outcome) on the CONSORT for Abstracts form we additionally considered as assessment options “partially” and “unclear”. The decision to create a third response option was based on the justification that some abstracts contemplated the eligibility criteria and did not report the place where the data were collected, or reported the type of randomization but not how the allocation was implemented, so the option would “partially” describe the item. For the primary outcome, the “unclear” option was added because many abstracts did not declare the primary outcome, precluding the assessment of related information (estimated effect size for each group and its precision).

Results

Of the 132 studies evaluated by the SEES Initiative in the year 2019, one of them did not present an abstract, thus 131 RCTs were eligible for evaluation in the present study (Figure 1). Only five studies were published in general medicine journals and 126 were published in exercise sciences journals. Most publications were from Medicine and Science in Sports and Exercise (n=48) and Scandinavian Journal of Medicine & Science in Sports (n=33).

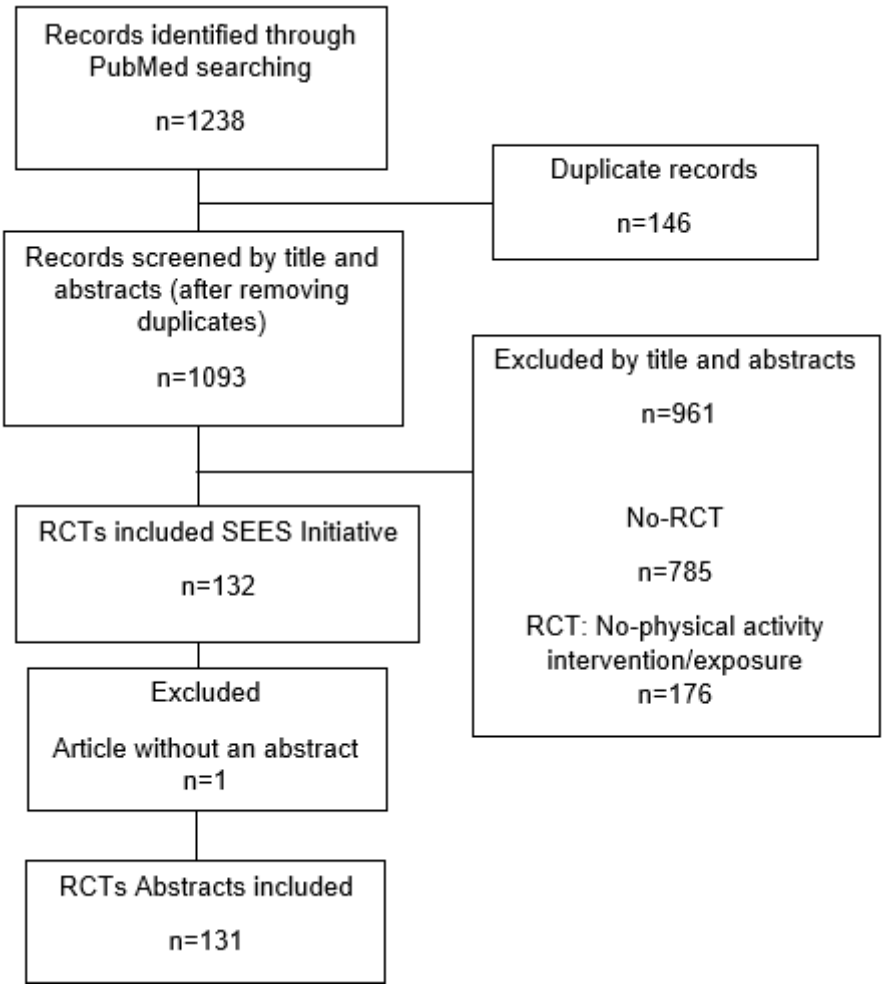

Figure 1. Flow-diagram of study selection process

Reporting of items by journal

Overall, all assessed journals but one (91%) provided recommendations on the structure of the abstract, indicating the maximum number of words in the abstract (median 275, range 150 to 450 words). Regarding the presence of endorsements for the CONSORT resources, 9/11 (82%) journals mentioned the use of CONSORT 2010 Statement, however, only two (18%) mentioned the CONSORT for Abstracts extension as a resource for abstract reports (Table 1). The adherence to the word limit recommended in journals' instructions for abstracts was verified in 44% of articles (55/124), whereas 56% presented abstracts with more words than allowed in author instructions (69/124). This analysis did not count the Journal of

Physiotherapy (n=7) because this journal did not limit the number of words in abstracts. Detailed information about the recommendations by journals, median of words in the abstracts of assessed articles, as well as the adherence to this recommendation is described respectively in the Supplementary File 2.

Table 1. Recommendations from journals on the structure and content of abstracts

	Journals Instructions (n=11)	
Descriptions	Yes	No
Number of words recommended for the abstract	10	1
Recommendation for a structured summary	8	3
Description of items for the abstract	8	3
Instruction to report the abstract items	4	7
Mention or endorsement of CONSORT for Abstracts	2	9
Mention or recommendation of the CONSORT 2010 Statement	9	2

Description: Values expressed in absolute frequency (n).

Reporting of items CONSORT for Abstracts

Of the 131 abstracts evaluated, 70 (53.4%) mentioned "randomized study" in the title, and only 34 (26%) reported the trial design (parallel, crossover, superiority, cluster, non-inferiority, or factorial) throughout the abstract. In relation to the description of the methods domain, 34 (26%) described completely the participants' item, which includes information about eligibility criteria and the settings of data collected. The items with the most positive evaluation in this domain were related to the interventions (123/131, 93.9%) and objectives or hypotheses (130/131, 99.2%). Only 2 articles described how participants were allocated to interventions and the type of randomization, whereas 6 (4.6%) reported only one piece of information, therefore, “partially” adhering to this item recommendation.

In the results domain, the recruitment period/status trial was described in 20 RCTs (9.2%), and 8 (6.1%) described the number of participants analyzed in each group. The

estimated effect size and its precision measure for primary outcome was identified in 33 (25.2%) abstracts; in 87 (66%) this item was marked as “unclear” due to reporting uncertainty about what was the primary outcome.

Overall, 129 (98.4%) abstracts presented their conclusions consistently with related results, and the mention of the trial registration number or the trial registration name was observed in 42 (32.1%) evaluated RCTs. The level of adherence to the 16 items of CONSORT for Abstracts are shown in Table 2 and the five items with highest and lowest adherence are shown in Figure 2. Detailed descriptions on each of the items by journal is specified in Supplementary File 3

Table 2. Adherence items CONSORT for Abstracts

	Yes	**No**	**Partially/ Unclear**
Title	70 (53.4)	61 (46.6)	
Trial design	34 (26)	97 (74)	
Methods			
Participants	34 (26)	2 (1.5)	95 (72.5)
Interventions	123 (93.9)	8 (6.1)	
Objective	130 (99.2)	1 (0.8)	
Outcomes	45 (34.4)	86 (65.6)	
Randomization	2 (1.5)	123 (93.9)	6 (4.6)
Blinding (masking)	28 (21.4)	103 (78.6)	
Results			
Number randomized	61(46.6)	70 (53.4)	
Recruitment	12 (9.2)	119 (90.8)	
Number analysed	8 (6.1)	123 (93.9)	
Outcomes	33 (25.2)	11 (8.4)	87 (66.4)
Harms	14 (10.7)	117 (89.3)	
Conclusions	129 (98.4)	2(1.5)	
Trial registration	42 (32.1)	89 (67.9)	

Funding	1 (0.8)	130 (99.2)

Description: Values expressed n (%)

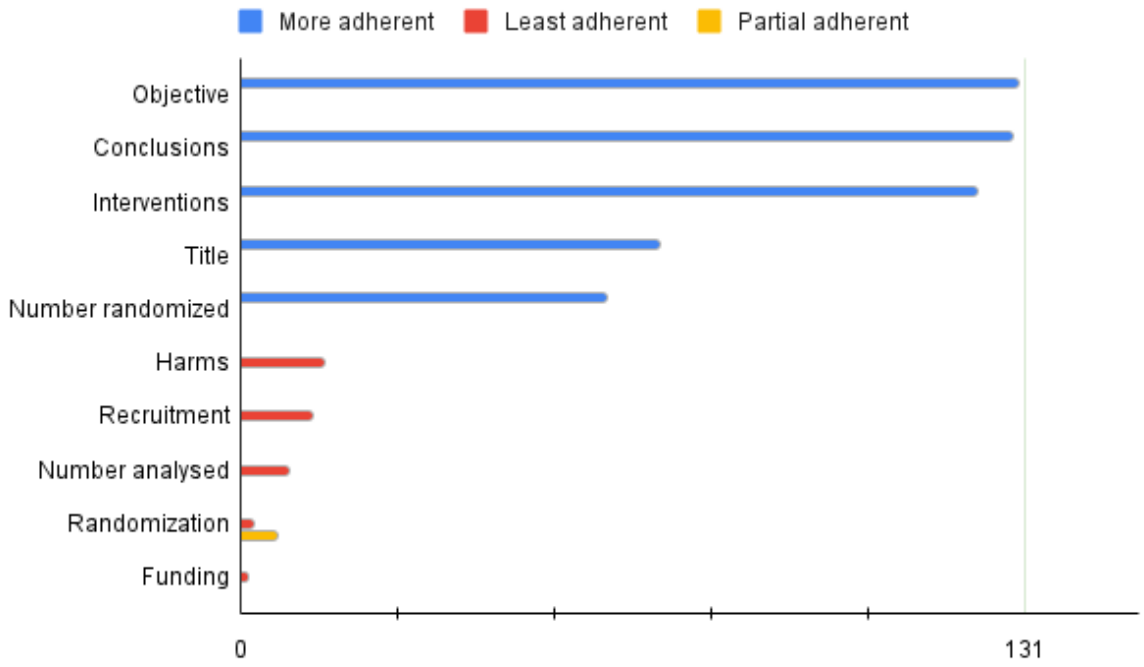

Figure 2. Items with highest and lowest adherence CONSORT for Abstracts

Discussion

We identified highly heterogeneous adherence to the 16 items recommended by CONSORT for Abstracts in articles reporting RCTs with physical activity interventions. There was high quality of reporting in specific objective or hypotheses, interventions' descriptions, and conclusions. On the other hand, some items had quite low adherence to reporting standards, especially in descriptions of allocation concealment and randomization, participants

analyzed in each group and sources of funding. Similar findings were observed in other fields, mainly in the quality of reporting of the domains of methods and results (3,5,6,15), such as in reviews that compared quality of reporting in abstracts of RCTs before and after the publication of CONSORT for Abstracts, identifying improvement in the reporting on some items, however, still suboptimal (8–10,16).

Although the mention of CONSORT for Abstracts in the “Instructions for authors" was observed in some evaluated journals, this did not guarantee the quality of reporting in abstracts of the published articles. A more active implementation of a rigid and specific editorial policy may be necessary to improve in the quality of available abstracts (17). It is worth noting that the limited number of words in abstract sections may be one of the factors influencing the quality of reporting. However, according to the CONSORT reference for abstracts, the authors consider 250 to 300 words would be sufficient to cover all suggested items in the checklist (2), and although this number of words was included in all evaluated journals, the information in the abstracts were still scarce.

The low adherence to the RCTs description in the title and study design in the abstract makes it difficult to enhance indexing in databases (e.g., specific filters), which might compromise the interpretation of the report by the readers (18). In the same way, the inadequate reporting of randomization and allocation concealment might be misinterpreted by readers as selection bias (19), and influence them in the decision to read the full article due to lack of clarity about the methodological quality of the study.

In the methods domain, the item 'participants' was adequately reported in few studies (26%). This low frequency may be related, in part, to the item including the description of the study setting (2), which caused a partial adherence to the complete information (72.5%). Some previous studies have split the evaluation of this item into sub-items, reporting high adherence only to the eligibility criteria of participants (3,8–10,15). A clear description of participants and the setting of data collected is necessary to ensure the external validity and applicability of the findings (2). In addition, the report of the primary outcome is considered of greatest importance to the readers (4), generally able to provide the most relevant and convincing clinical evidence regarding the primary objective of the trial. An infrequent report of this information, observed only in one third of abstracts, caused a lack of clarity of results for the primary outcome with the estimated effect size and its precision for each group defined as “unclear” in 66.4% (87/131) of our sample. Studies in other fields have shown better reporting of the primary

outcome (3,20), as well as improved reporting after publication of the CONSORT for Abstracts (16).

In the results domain, almost half of abstracts reported the number of participants randomized in each group, however, the number of participants analysed in each group was rarely reported. Although sometimes the number of randomized and analysed participants can be exactly the same, the lack of reporting this information hinders the interpretation of readers who only have access to the abstract of the article. Likewise, the poor reporting of time periods when the study took place and the frequency of adverse events compromises readers' assessment of key aspects related to the article adequateness for a full reading and evidence translation (2,4).

Less than half of the studies mentioned trial registration (32%), and only one reported funding. The registration enables readers to get more detailed information about the trial, to identify bias and analytical flexibility especially when there is no open access to the full article, in addition to allowing the identification of research gaps and avoiding unnecessary duplication of research efforts and expenditures (21). Similarly, reporting on the existence or not of funding sources allows the reader to take a more critical look at the study, due to the influence that can have on the design, collection, and analysis of data (2,4).

To our knowledge, this study is a pioneer in assessing the quality of reporting in abstracts of RCTs with physical activity interventions. However, some limitations must be considered. Our sample of RCTs represents only the year 2019 and only pre-selected scientific journals. The results observed in our evaluations are not readily generalizable to other RCTs in exercise sciences. In addition, the creation of a subcategory for the analysis of three CONSORT for Abstracts items may be a factor that limits the comparability of our findings with other studies. However, we identified that there is no standardization between studies on how to assess CONSORT for journal abstracts checklist. Some items consist of several aspects that were judged only in general context, while others assessed each specific aspect (16), therefore, some mention the analysis of 16 items, others of 17 or even 22 items, as divided into sub-items. Thus, such data enhance the need for a more detailed look at the communication of clinical trials, whether at the level of editors, reviewers or authors.

Conclusion

Quality of reporting in abstracts of RCTs in the physical activity field is variable and suboptimal according to the items suggested by CONSORT for Abstracts. Furthermore, there is a poor endorsement of this guideline by the journals selected by the SEES Initiative. Such data are worrisome, as many readers only read or have access to the abstracts of the articles, which impairs the interpretation of scientific evidence. Based on this study, we call the attention of editors, reviewers, and authors to consider strict adherence to CONSORT for Abstracts, in order to promote transparency, integrity, and quality in the dissemination and communication of clinical trials in the physical exercise field.

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Conflicts of Interest

All authors disclose no conflicts of interests for the present study.

Data Availability

Data from this study will be shared in the Open Science Framework (https://osf.io/ntw7d/).

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Supplementary file 1. Forms used to extract recommendations from journals about the abstracts session and to evaluate CONSORT for Abstracts.

Form 1 - Journal's Instructions for abstract	
Questions	**Options**
Is there a description of the number of words recommended for the abstract?	YES/NO
What is the recommended number?	
Is there a recommendation for a structured summary?	YES/NO
Is there a description of items for the abstract?	YES/NO
Is there an instruction to report the summary items?	YES/NO
Is there a mention or endorsement regarding the CONSORT Abstract Extension as a resource to be used for abstracts reporting?	YES/NO
Is there a mention or recommendation regarding the CONSORT 2010 Statement?	YES/NO

Form 2 - Information extracted from the abstract	
PMID	
Title	
Journal	
Number of words in the abstract	
Questions	**Options**
Is the study identified as random in the title? (Note: "random allocation", "randomly assigned" should be considered	YES/NO

Is there a description of the trial design (e.g., parallel, factorial, cluster, crossover, factorial, superiority, equivalence or noninferiority)?	YES/NO
Is there a description of eligibility criteria of the participants included and the settings where the data were collected?	YES/ NO/ PARTIALLY
Does the abstract list the study interventions?	YES/NO
Is there a clear description of the specific objective or hypothesis?	YES/NO
Does the abstract inform the primary outcome (variable of interest)?	YES/NO
Is there a description of how participants were allocated to interventions? Type of randomization?	YES/ NO/ PARTIALLY
Is there a description of blinding/masking to group assignments?	YES/NO
Is there a description of the number of participants randomized in each group?	YES/NO
Is there a description regarding the dates/periods of recruitment / trial status?	YES/NO
Is there a description on the number of participants analyzed in each group?	YES/NO
For the primary outcome, is there a result for each group and the estimated effect size and its precision?	YES/ NO/ UNCLEAR
Is there a description for harm outcomes or adverse events?	YES/NO
Is there a general interpretation of the results?	YES/NO
Is there a description of trial registration (number and name)?	YES/NO
Is there a statement regarding the sources of funding (within the summary structure)?	YES/NO

Supplementary file 2. Recommendations and adherence to the number of words for summaries detailed by journals.

S2.1. Recommendations from journals on the structure and content of abstracts

Journal (n=11)	Number of words	Maximum word limit	Structured abstract	Items abstract	Report of items	CONSORT for Abstracts	CONSORT 2010 Statement
Am J Sports Med	Yes	350	Yes	Yes	Yes	No	Yes
Br J Sports Med	Yes	250	Yes	Yes	No	No	No
Eur J Prev Cardiol	Yes	250	Yes	Yes	No	No	Yes
Int J Behav Nutr Phys Act	Yes	350	Yes	Yes	Yes	Yes	Yes
J Physiother	No	-	No	No	No	No	Yes
J Sci Med Sport	Yes	250	Yes	Yes	No	No	Yes
Med Sci Sports Exerc	Yes	275	Yes	Yes	No	No	No
Scand J Med Sci Sports	Yes	250	No	No	No	No	Yes
Sports Med	Yes	300 (150-450)	No	No	No	No	Yes
JAMA	Yes	350	Yes	Yes	Yes	No	Yes
The BMJ	Yes	275 (250-300)	Yes	Yes	Yes	Yes	Yes

Description: Values expressed in absolute frequency (n), median (min and max)

Am J Sports Med, American Journal of Sports Medicine; Br J Sports Med, British Journal of Sports Medicine; Eur J Prev Cardiol, European Journal of Preventive Cardiology; Int J Behav Nutr Phys Act, International Journal of Behavioral Nutrition and Physical Activi; J Physiother, Journal of Physiotherapy; J Sci Med Sport, Journal of Science and Medicine in Sport; Med Sci Sports Exerc, Medicine and Science in Sports and Exercise; Scand J Med Sci Sports, Scandinavian Journal of Medicine & Science in Sports; Sports Med, Sports Medicine; JAMA, Journal of the American Medical Association; The BMJ, The British Medical Journal.

S2.2. Number of words in abstracts and adherence to recommendations

Abstracts evaluated by journals (n = 124)	Number of words included	Adhered to the recommendations	Not adhere
Am J Sports Med (n = 3)	279 (267-343)	3	0
Br J Sports Med (n = 15)	249 (232-272)	9	6
Eur J Prev Cardiol (n = 6)	263 (243-313)	1	5
Int J Behav Nutr Phys Act (n = 8)	362 (256-394)	3	5
J Physiother (n = 7)	292 (254-298)	-	-
J Sci Med Sport (n = 15)	244 (224-251)	12	3
Med Sci Sports Exerc (n = 39)	276 (217-349)	15	24
Scand J Med Sci Sports (n = 31)	256 (214-313)	10	21
Sports Med (n = 3)	370 (301-507)	2	1
JAMA (n = 2)	443(442-444)	0	2
The BMJ (n = 2)	343 (316-369)	0	2

Description: Values expressed in absolute frequency (n)

Supplementary file 3

S3. Adherence of journal abstracts to the CONSORT for Abstracts

RCTs (n=131)	Yes	No	Partial/ Unclear
Is the study identified as random in the title?			
Am J Sports Med (n=3)	3		
Br J Sports Med (n=15)	13	2	
Eur J Prev Cardiol (n=6)	2	4	
Int J Behav Nutr Phys Act (n=8)	7	1	
J Physiother (n=7)	7		
J Sci Med Sport (n=15)	8	7	
Med Sci Sports Exerc (n=39)	6	33	
Scand J Med Sci Sports (n=31)	17	14	
Sports Med (n=3)	3		
JAMA (n=2)	2		
The BMJ (n=2)	2		
Is there a description of the trial design?			
Am J Sports Med (n=3)	1	2	
Br J Sports Med (n=15)	6	9	

Eur J Prev Cardiol (n=6)		6	
Int J Behav Nutr Phys Act (n=8)	2	6	
J Physiother (n=7)	1	6	
J Sci Med Sport (n=15)	9	6	
Med Sci Sports Exerc (n=39)	4	35	
Scand J Med Sci Sports (n=31)	6	25	
Sports Med (n=3)	2	1	
JAMA (n=2)	2		
The BMJ (n=2)	1	1	
Is there a description of eligibility criteria of the participants included and the settings where the data were collected?			
Am J Sports Med (n=3)	1		2
Br J Sports Med (n=15)	5		10
Eur J Prev Cardiol (n=6)	1		5
Int J Behav Nutr Phys Act (n=8)	4	1	3
J Physiother (n=7)	5		2
J Sci Med Sport (n=15)	6		9
Med Sci Sports Exerc (n=39)	4	1	34
Scand J Med Sci Sports (n=31)	4		27

Sports Med (n=3)	1		2
JAMA (n=2)	1		1
The BMJ (n=2)	2		
Does the abstract list the study interventions?			
Am J Sports Med (n=3)	3		
Br J Sports Med (n=15)	11	4	
Eur J Prev Cardiol (n=6)	6		
Int J Behav Nutr Phys Act (n=8)	8		
J Physiother (n=7)	7		
J Sci Med Sport (n=15)	14	1	
Med Sci Sports Exerc (n=39)	38	1	
Scand J Med Sci Sports (n=31)	29	2	
Sports Med (n=3)	3		
JAMA (n=2)	2		
The BMJ (n=2)	2		
Is there a clear description of the specific objective or hypothesis?			
Am J Sports Med (n=3)	3		
Br J Sports Med (n=15)	15		

Eur J Prev Cardiol (n=6)	6	
Int J Behav Nutr Phys Act (n=8)	8	
J Physiother (n=7)	7	
J Sci Med Sport (n=15)	15	
Med Sci Sports Exerc (n=39)	38	1
Scand J Med Sci Sports (n=31)	31	
Sports Med (n=3)	3	
JAMA (n=2)	2	
The BMJ (n=2)	2	
Does the abstract inform the primary outcome (variable of interest)?		
Am J Sports Med (n=3)	1	2
Br J Sports Med (n=15)	10	5
Eur J Prev Cardiol (n=6)	2	4
Int J Behav Nutr Phys Act (n=8)	4	4
J Physiother (n=7)	5	2
J Sci Med Sport (n=15)	6	9
Med Sci Sports Exerc (n=39)	6	33
Scand J Med Sci Sports (n=31)	6	25

Sports Med (n=3)	1	2	
JAMA (n=2)	2		
The BMJ (n=2)	2		
Is there a description of how participants were allocated to interventions? Type of randomization?			
Am J Sports Med (n=3)		3	
Br J Sports Med (n=15)		15	
Eur J Prev Cardiol (n=6)		5	1
Int J Behav Nutr Phys Act (n=8)		6	2
J Physiother (n=7)		7	
J Sci Med Sport (n=15)	1	14	
Med Sci Sports Exerc (n=39)		39	
Scand J Med Sci Sports (n=31)		30	1
Sports Med (n=3)	1	1	1
JAMA (n=2)		2	
The BMJ (n=2)		1	1
Is there a description of blinding/masking to group assignments?			
Am J Sports Med (n=3)	1	2	
Br J Sports Med (n=15)	3	12	

Eur J Prev Cardiol (n=6)		6
Int J Behav Nutr Phys Act (n=8)	2	6
J Physiother (n=7)	7	
J Sci Med Sport (n=15)	4	11
Med Sci Sports Exerc (n=39)	2	37
Scand J Med Sci Sports (n=31)	5	26
Sports Med (n=3)	2	1
JAMA (n=2)	1	1
The BMJ (n=2)	1	1
Is there a description of the number of participants randomized to each group?		
Am J Sports Med (n=3)	2	1
Br J Sports Med (n=15)	7	8
Eur J Prev Cardiol (n=6)	4	2
Int J Behav Nutr Phys Act (n=8)	4	4
J Physiother (n=7)		7
J Sci Med Sport (n=15)	5	10
Med Sci Sports Exerc (n=39)	16	23
Scand J Med Sci Sports (n=31)	18	13

Sports Med (n=3)	2	1
JAMA (n=2)	2	
The BMJ (n=2)	1	1
Is there a description regarding the dates/periods of recruitment/trial status?		
Am J Sports Med (n=3)		3
Br J Sports Med (n=15)	3	12
Eur J Prev Cardiol (n=6)		6
Int J Behav Nutr Phys Act (n=8)	1	7
J Physiother (n=7)		7
J Sci Med Sport (n=15)	2	13
Med Sci Sports Exerc (n=39)	1	38
Scand J Med Sci Sports (n=31)	2	29
Sports Med (n=3)		3
JAMA (n=2)	2	
The BMJ (n=2)	1	1
Is there a description of the number of participants analysed in each group?		
Am J Sports Med (n=3)		3
Br J Sports Med (n=15)		15

Eur J Prev Cardiol (n=6)		6	
Int J Behav Nutr Phys Act (n=8)	2	6	
J Physiother (n=7)		7	
J Sci Med Sport (n=15)	2	13	
Med Sci Sports Exerc (n=39)	1	38	
Scand J Med Sci Sports (n=31)		31	
Sports Med (n=3)	1	2	
JAMA (n=2)	2		
The BMJ (n=2)		2	
For the primary outcome, is there a result for each group and the estimated effect size and its precision?			
Am J Sports Med (n=3)	1		2
Br J Sports Med (n=15)	8	2	5
Eur J Prev Cardiol (n=6)	1	1	4
Int J Behav Nutr Phys Act (n=8)	2	1	5
J Physiother (n=7)	4	1	2
J Sci Med Sport (n=15)	3	3	9
Med Sci Sports Exerc (n=39)	4	2	33
Scand J Med Sci Sports (n=31)	5	1	25

Sports Med (n=3)	1		2
JAMA (n=2)	2		
The BMJ (n=2)	2		
Is there a description for harm outcomes or adverse events?			
Am J Sports Med (n=3)	1	2	
Br J Sports Med (n=15)		15	
Eur J Prev Cardiol (n=6)		6	
Int J Behav Nutr Phys Act (n=8)	1	7	
J Physiother (n=7)		7	
J Sci Med Sport (n=15)	3	12	
Med Sci Sports Exerc (n=39)	1	38	
Scand J Med Sci Sports (n=31)	2	29	
Sports Med (n=3)	2	1	
JAMA (n=2)	2		
The BMJ (n=2)	2		
Is there a general interpretation of the results?			
Am J Sports Med (n=3)	3		
Br J Sports Med (n=15)	15		

Eur J Prev Cardiol (n=6)	5	1
Int J Behav Nutr Phys Act (n=8)	8	
J Physiother (n=7)	7	
J Sci Med Sport (n=15)	15	
Med Sci Sports Exerc (n=39)	39	
Scand J Med Sci Sports (n=31)	30	1
Sports Med (n=3)	3	
JAMA (n=2)	2	
The BMJ (n=2)	2	
Is there a description of trial registration (number and name)?		
Am J Sports Med (n=3)	1	2
Br J Sports Med (n=15)	13	2
Eur J Prev Cardiol (n=6)	1	5
Int J Behav Nutr Phys Act (n=8)	8	
J Physiother (n=7)	7	
J Sci Med Sport (n=15)	4	11
Med Sci Sports Exerc (n=39)	2	37
Scand J Med Sci Sports (n=31)		31

Sports Med (n=3)	2	1
JAMA (n=2)	2	
The BMJ (n=2)	2	
Is there a statement regarding the sources of funding (within the summary structure)?		
Am J Sports Med (n=3)	1	2
Br J Sports Med (n=15)	6	9
Eur J Prev Cardiol (n=6)		6
Int J Behav Nutr Phys Act (n=8)	2	6
J Physiother (n=7)	1	6
J Sci Med Sport (n=15)	9	6
Med Sci Sports Exerc (n=39)	4	35
Scand J Med Sci Sports (n=31)	6	25
Sports Med (n=3)	2	1
JAMA (n=2)	1	1
The BMJ (n=2)	2	

Description: Values expressed in absolute frequency (n)

7. CONCLUSÕES E CONSIDERAÇÕES FINAIS

Os achados da presente tese demonstram que a implementação de estratégias e a adesão às recomendações para uma comunicação clara e efetiva dos resultados de ensaios clínicos no nível de participantes e de pesquisadores requer melhorias. Tais práticas de transparência em pesquisa são importantes, pois possibilitam a definição de políticas públicas e potenciais tomada de decisão por diferentes partes interessadas.

A partir do estudo SWAT, concluímos que participantes idosos de um programa de atividade física apresentaram perspectivas positivas em relação a dois formatos de entrega de resultados individuais quando avaliado os desfechos de compreensão, satisfação e impacto emocional. No entanto, o pequeno tamanho amostral prejudicou o poder do estudo e explorações adicionais. Diante disso, sugerimos que estudos futuros considerem o envolvimento do paciente e do público nos diferentes processos da pesquisa, identificando as preferências de formatos de entrega de resultados individuais e avaliando os efeitos dessa prática aos participantes com idades avançadas ou com possível dificuldade de compreensão e implementabilidade dos dados. No escopo de comunicação e disseminação de resultados de ECRs na seção dos resumos, o segundo estudo demonstrou qualidade de relato variável e subótima aos itens recomendados pela extensão do CONSORT para resumos, além de baixo endossamento deste documento em diferentes revistas da área médica e da ciência do exercício. Deste modo, levando em consideração que muitos leitores baseiam-se apenas nas informações dessa seção para avaliar a aplicabilidade e confiabilidade dos achados, o que pode interferir na tomada de decisão na pesquisa e prática clínica, chamamos a atenção de editores, revisores e autores sobre a importância de resumos bem relatados seguindo as recomendações do CONSORT para resumos.

A partir dessas observações, destacamos a necessidade de melhorar o processo de comunicação científica de ensaios clínicos por meio da qualidade de relato dos resultados de pesquisa, principalmente, na área do exercício e atividade

física, considerando que estudos nessa área são essenciais para prevenção e tratamento de severas condições de saúde.