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Spotlight on...

Developing skills of allied health professionals for a principal investigator role: A case from the SIP SMART2 swallowing prehabilitation trial

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Abstract.
BACKGROUND: Clinicals trials are the bedrock for evidence-based practice amongst healthcare professionals. Creating research opportunities through structured training is integral in developing future research leaders including allied health professionals (AHP)s. The UK National Institute for Health and Care Research (NIHR) Associate Principal Investigator (Associate PI) scheme was launched in 2019 to support trainee medical, dental, nursing and AHPs to gain practical experience delivering clinical trials under local PIs. Associate PI certification requires completion of activities which includes Good Clinical Practice Training, attendance at trial meetings, trial recruitment and maintenance of site file related activities. The aim of this article was to showcase how the activities completed by an AHP undertaking the Associate PI scheme support researcher development.
METHODS: SIP SMART2 is a multi-centre trial of swallowing prehabilitation in head and neck cancer. SIP SMART2 was one of the first AHP-led trials to be registered on the Associate PI scheme in April 2019 with six Associate PIs registered. The example of one trainee's activities and skills acquisition by completing the scheme were compared to a well-established researcher development framework known as the Vitae Researcher Development Framework (RDF).
RESULTS: Activities completed during the Associate PI scheme supported development across all 4 domains of the RDF. In particular, Domain C (Research governance and organisation) and Domain D (Engagement, influence and impact).
CONCLUSION: The Associate PI scheme provides an opportunity for AHPs to gain skills and experience to develop across all domains of the Vitae RDF. Future work should assess whether completion of the Associate PI scheme leads to long-term engagement in clinical research.

Keywords: Clinical trial, associate PI, vitae RDF, allied health professionals

1. Introduction

Clinical trials represent the bedrock of evidence-based practice and many new healthcare interventions are first tested within a trial before they are adopted in practice (Evans, 2003; McGovern DPB., 2001).

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However, within healthcare systems such as the UK National Health Service (NHS), undertaking such investigations falls to clinicians who may not be research-trained to design and conduct trials. The principal investigator (PI) at each site has oversight responsibility for the conduct and administration of the trial, ensuring that the trial is delivered according to the requirements of the protocol, sponsor guidelines and the principles of Good Clinical Practice (GCP) (Health Research Authority, 2021) In the past, the PI role was usually the preserve of medically trained staff within the NHS. Over the last couple of years it has become clear that nurses and allied health professionals (AHP)s represent a willing and untapped resource available to support the delivery of clinical trials (McNiven et al., 2021).

The National Institute for Health and Care Research (NIHR) is a major source of government funding in the NHS and supports a large portfolio of studies by providing research and infrastructure funding. In February 2019, the NIHR Associate Principal Investigator (Associate PI) Scheme was developed to encourage junior clinicians/trainees to gain experience on NIHR portfolio trials (*National Institute for Health and Care Research (NIHR). Associate Principal Investigator Scheme.*, 2022) This was in the form of a six month in-work training opportunity under the mentorship of a local PI. The scheme was seen as mutually beneficial: trainees are well-placed to increase recruitment, support communication between the clinical site and clinical trials unit and in turn develop leadership skills under the supervision of an experienced PI. Following a successful pilot, the Associate PI scheme was launched nationally in the UK on 3rd November 2021 and chief investigators were encouraged to consider registering their multi-centre studies onto the scheme (*National Institute for Health and Care Research (NIHR). NIHR Associate Principal Investigator Scheme Virtual Launch Event*, 2021). A key aim of the Associate PI scheme is to develop the next generation of clinical research leaders and PIs from a medical, nursing and AHP background. The scheme is endorsed by several Royal Colleges ensuring that trainees receive appropriate recognition and credit within their individual fields and specialisms.

The Associate PI scheme fits well into the agenda of building research capacity for AHPs which is gaining momentum internationally (Matus et al., 2018; Slade et al., 2018; Wenke et al., 2017; Wenke & Mickan, 2016). In 2017, it was reported that non-medical clinical academic AHPs made up less than 0.1% of the workforce in comparison with 4.6% of clinical academic medical professionals (Medical Research Council, 2017; Medical Schools Council, 2017). Benefits of AHP research positions within clinical settings have been reported to be impactful across individual, organisational/community and team/service level. These include enhanced research culture, activity and outputs; staff development (clinical, professional and research); improved profile of AHPs and clinical/service changes (Wenke et al., 2017). AHPs are optimally placed to conduct clinical research given their clinical roles, often being actively involved in direct patient care (Jones & Keenan, 2021). The Associate PI scheme offers an opportunity to play a vital role in the delivery of clinical research, acquire research skills and experience whilst enhancing and embedding a research culture (*National Institute for Health and Care Research (NIHR). Associate Principal Investigator Scheme.*, 2022).

SIP SMART2 is a pilot multi-centre swallowing prehabilitation trial (ISRCTN12377415) and one of the first AHP-led trials to be registered on the Associate PI scheme. This article provides a case study on the skills AHPs may be expected to acquire on the Associate PI scheme by using the example of a trainee on the SIP SMART2 trial and comparing their skill acquisition to a well-known researcher development framework known as the Vitae RDF (*Vitae: Researcher Development Framework. Careers Research and Advisory Centre (CRAC) Limited*, 2011).

2. Methods

2.1. Registration of the SIP SMART2 trial on the NIHR Associate PI scheme

SIP SMART2 is a multi-centre clinical trial, funded by the NIHR and part of their portfolio of studies. It was therefore eligible to be registered on the NIHR Associate PI scheme allowing one trainee (at a time) at each trial site to work under supervision and with the agreement of the site PI and in some cases the Clinical Trials Unit. Following trial registration on the Associate PI scheme in April 2022, six trainees (uptake at all but one site) signed onto the scheme and at the time of submitting this manuscript, two (one dietitian and one speech and language therapist) have received their Associate PI accreditation. They were required to access the NIHR Associate PI

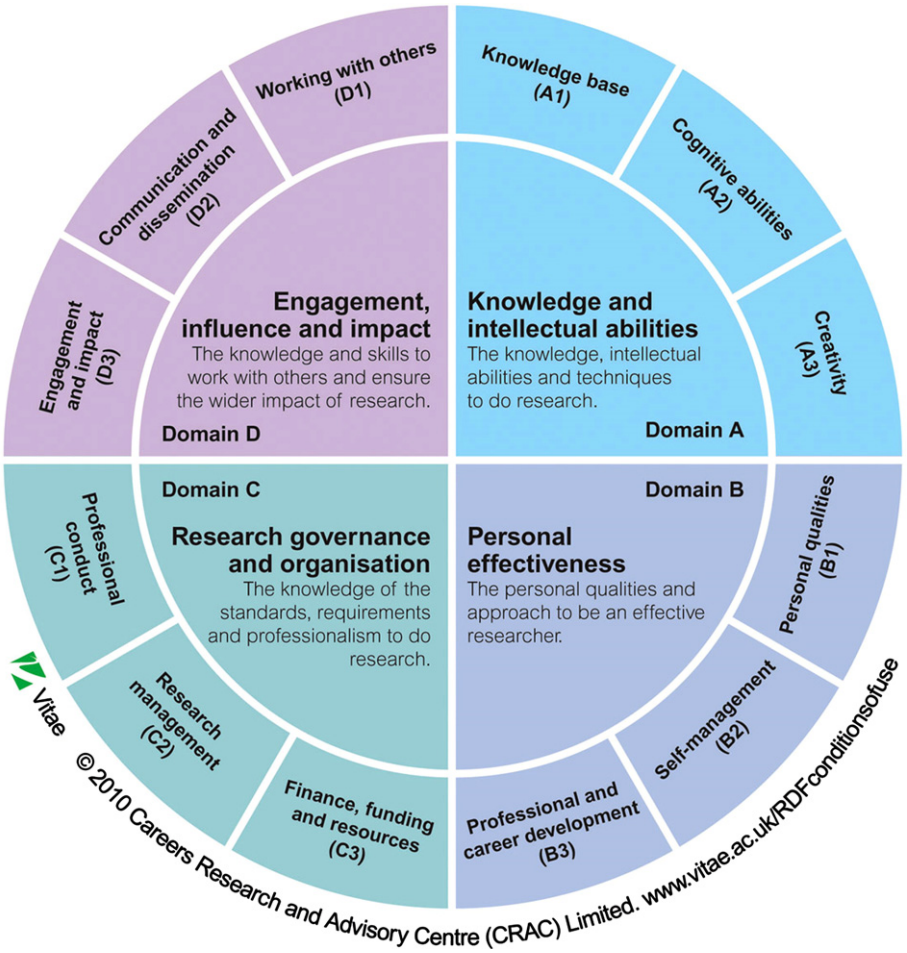

Fig. 1. Vitae Research Development Framework (re-produced with permission from Vitae). Source: (*Vitae: Researcher Development Framework. Careers Research and Advisory Centre (CRAC) Limited*, 2011).

checklist from the NIHR Learn Hub and to ensure together with their PI mentor, that they were able to meet the requisite criteria within a six-month timeframe. The typical activities on the checklist have been matched against the Vitae framework and form the basis of our Results and Discussion that follows.

2.2. *Vitae researcher development framework (RDF)*

The Vitae Researcher Development Framework (RDF) (Fig. 1) was developed by experts through a variety of methodologies including semi-structured interviews and validated by an independent panel of researchers, experts and stakeholders (Reeves et al., 2012). The Vitae RDF was introduced in 2009 and is used widely as a tool by researchers at any stage of their career to support and track development. The RDF captures the behaviours, attributes, and knowledge of successful researchers and is structured into 4 domains:

- Domain A: Knowledge and intellectual abilities
- Domain B: Personal effectiveness
- Domain C: Research governance and organisation
- Domain D: Engagement, influence and impact

3. Results

Table 1 and Supplementary Fig. 1 depicts the 26 Associate PI activities completed by the single trainee (10 core and 4 additional activities required for certification of Associate PI status and 12 specific to SIP SMART2) against the Vitae RDF domains. The Asso-

Table 1
NIHR Associate PI activity with corresponding Vitae RDF domain

NIHR Associate PI Checklist Activity	Vitae RDF Domain											
Core activities (10)	A1	A2	A3	B1	B2	B3	C1	C2	C3	D1	D2	D3
Be a member of the site research team						X				X		
6-month involvement at a single site (set-up or follow-up phase)								X				
Dissemination of the study and engaging with the clinical departments						X					X	
Regular engagement with the research team including the PI and delivery team, site log maintenance, recruitment progress, protocol amendments, data returns and quality	X					X	X	X		X		
Completion and updating of the delegation log					X			X		X		
Ensuring research delivery team has up to date GCP and signed CVs							X	X		X		
Education of other health professionals working on the study and ensuring those on the delegation log are informed of the protocol requirements and study procedures	X				X		X			X	X	X
Monthly research team meetings with the PI, delivery, and clinical team						X		X		X		
Reviewing screening logs and ensuring compliance of recruitment per inclusion criteria								X				
Recruitment, consenting and follow up of participants				X		X	X	X		X	X	
Additional activities (4)												
Deputising for the PI, interacting with the Clinical Trials Unit, Clinical Research Network and collaborating with Associate PIs at other centres	X			X		X	X	X		X	X	

Patient and Public Involvement activities											X	X	X
Activities related to Trial management group meetings						X	X	X		X			
Training courses e.g. GRANULE, GCP, INSPIRE, FUNDAMENTALS	X	X				X	X						
SIP SMART2 activities (12)													
Liaising potential eligible patients to treating Consultant, PI and Research Nurse after MDT every week to be approached in clinic.				X	X			X		X			
Attended Site Initiation Visit	X					X		X		X			
Completed GCP, GRANULE and PPI workshops	X	X	X		X	X	X	X					X
Delegated responsibilities: obtain patient written informed consent; confirm patient eligibility; co-ordination of trial; screening of patients; review and sign off on source data and case report forms; maintain screening/enrolment logs; inform patients of trial; sign consent on behalf of CI	X				X		X	X		X	X		X
Adding amendments and acting on these following feedback from site initiation report				X		X	X	X		X			
Recruited, informed and consented 3 patients	X			X	X	X	X	X		X	X		
Knowledge gained about trial governance e.g. protocol, insurance requirements, data protection, case report forms, funding source	X						X	X	X				
Organisation: trial recruitment and monitoring target with research nurse					X			X		X			
Collaborated with Associate PIs at other centers with the plan to present our work at a national conference			X			X				X	X		X
Communicating risks/benefits of participation and explaining equipoise		X	X	X		X	X	X		X	X		
Taking responsibility for screening patients from MDT				X	X			X		X			
Associate PI certification status on completion of the checklist				X	X	X	X	X		X			

All core activities required for accreditation of Associate PI status on completion of the scheme. Vitae RDF domains: Domain A: Knowledge and intellectual abilities; Domain B: Personal Effectiveness; Domain C: Research governance and organisation; Domain D: Engagement, influence and impact. A1 = Knowledge base; A2: Cognitive abilities; A3 Creativity; B1 Personal qualities; B2 Self-management; B3 Professional and career development; C1 Professional conduct; C2 Research management; C3 Finance, funding, and resources; D1 Working with others; D2 Communication and dissemination; D3 Engagement and impact. Abbreviations: Associate PI = Associate Principal Investigator; PI = Principal Investigator; MDT = multi-disciplinary team; CV = Curriculum Vitae; GCP = Good Clinical Practice.

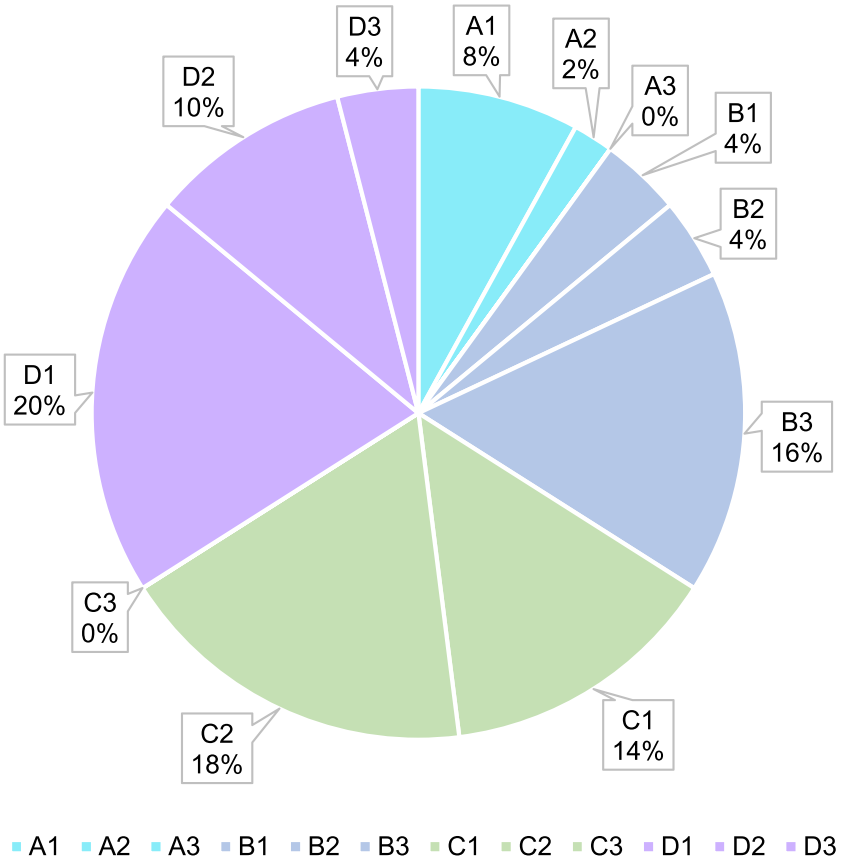

Fig. 2. Chart to show the breakdown of Associate PI core/additional checklist activities against Vitae RDF domains. Vitae RDF domains: Domain A: Knowledge and intellectual abilities; Domain B: Personal effectiveness; Domain C: Research governance and organisation; Domain D: Engagement, influence and impact. A1 = Knowledge base; A2: Cognitive abilities; A3 Creativity; B1 Personal qualities; B2 Self-management; B3 Professional and career development; C1 Professional conduct; C2 Research management; C3 Finance, funding, and resources; D1 Working with others; D2 Communication and dissemination; D3 Engagement and impact. Abbreviations: Associate PI = Associate Principal Investigator.

ciate PI scheme is shown to include activities that fit all the Vitae RDF domains. Domain A (Knowledge and intellectual abilities) was met on 15 instances by 11 activities; Domain B (Personal effectiveness) on 32 instances by 21 activities; Domain C (Research governance and organisation) on 35 instances by 22 activities and Domain D (Engagement, influence and impact) on 34 instances by 22 activities.

Figure 2 depicts the breakdown of how the core and additional Associate PI checklist activities corresponded proportionately to Vitae RDF domains for the single trainee's checklist. The 14 activities on the Associate PI checklist included 10 core and 4 additional activities. These activities were logged against whether they met each Vitae RDF sub-domains and corresponding overall percentage:

Vitae RDF domains were met on a total of 50 instances by completing the 14 core/additional Associate PI activities. A1 was met by 2 core activities and 2 additional activities (8%); A2 was met by 0 core activities and 1 additional activity (2%); A3 was met by 0 core activities and 0 additional activities (0%); B1 was met by 1 core activity and 1 additional activity (4%); B2 was met by 2 core activities and 0 additional activities (4%); B3 was met by 5 core activities and 3 additional activities (16%); C1 was met by 4 core activities and 3 additional activities (14%); C2 was met by 7 core activities and 2 additional activities (18%); C3 was met by 0 core activities and 0 additional activities (0%); D1 was met by 7 core activities and 3 additional activities (20%); D2 was met by 3 core activities and

2 additional activities (10%); D3 was met by 1 core activity and 1 additional activity (4%).

Overall, the instances where RDF domains were met by the Associate PI core and additional activities corresponded to 10% for Domain A (Knowledge and intellectual abilities); 24% for Domain B (Personal effectiveness); 32% for Domain C (Research governance and organisation); and 34% for Domain D (Engagement, influence and impact).

4. Discussion

The aim of this article was to showcase participation of AHPs in what has traditionally been thought of as a role for medically qualified clinicians by highlighting a training scheme known as the NIHR Associate PI Scheme. We considered the skills, activities and experiences gained by an AHP undertaking the Associate PI scheme on an AHP-led clinical trial (SIP SMART2) against the widely used Vitae RDF. We report that completion of the core and additional activities from the Associate PI scheme as well as SIP SMART2 specific activities provided opportunities for development against all Vitae RDF domains. In particular, the exposure to trial governance and practical experience gained supported researcher development in domains C (Research governance and organisation) and D (Engagement, influence and impact).

Our findings are in accordance with previous articles reporting beneficial effects on uptake of the Associate PI scheme for developing trainee researchers. In the NIHR Sunflower RCT, one of the pilot projects of the scheme, Jepson and colleagues (2021) undertook qualitative interviews on 17 trainees and 17 consultants. Trainees reported that participation of the Associate PI scheme had potential benefit for their career development, informing their own clinical practice and cited this as the main reason for engaging with the scheme. The paperwork required for completion of the scheme was reported as burdensome by some and a potential barrier towards uptake. However, the formal recognition provided by the scheme was regarded as beneficial, in particular, the ability to show evidence of recruiting participants and collaboration in research which would contribute to the completion of the Certificate Completion of Training (CCT) (Dinneen & Shaw, 2020). Activities completed by Associate PIs included screening and assessing for eligibility, study compliance activities e.g. maintaining the screening log, discussing the study with potential participants, consenting and recruiting participants and completion of GCP training (Jepson et al., 2021).

Recruitment of participants into RCTs is known to be challenging and not meeting target recruitment can lead to underpowered studies with implications for validity of results (Sully et al., 2013). Training of staff has been identified as a key priority to improve recruitment (Bower et al., 2014). The Associate PI scheme has been reported to have significant benefits by improving trial recruitment, especially out-of-hours elective admissions. Indeed, consent for the Sunflower Study was taken by trainees in 35% ($n = 185$) of acute patients and 11% of elective patents ($n = 175$) demonstrating the mutual benefit the Associate PI scheme provides (Jepson et al., 2021). These findings are consistent with Vas and colleagues (2021) who reported improved recruitment of eligible participants following introduction of a local trainee PI scheme which has similarities to the Associate PI scheme (Vas et al., 2021).

AHPs constitute around a third of the health and social care workforce in the UK (*National Health Service Workforce Statistics*, 2022). Realising the potential of AHPs in delivering research is integral to the NIHR's mission (*Council for Allied Health Professions Research: About CAHPR*, 2022). Prior studies have reported that AHPs report a lack of confidence in their research knowledge and skills and opportunities to develop can be lacking (Borkowski et al., 2016). This is the first article to our knowledge that has reported completion of the Associate PI scheme by an AHP, on an AHP-led trial, and under the supervision of an AHP PI. Six AHPs registered to be Associate PIs on SIP SMART2, with two completing the scheme and awarded certification as of November 2022. This demonstrates a clear opportunity for senior AHP researchers to supervise and mentor early career AHP researchers to develop into PIs for RCTs within the clinical setting. This is in accordance with a recent study that developed a research framework for AHPs in the UK which included building capability, training opportunities and research culture amongst AHPs (Harris et al., 2020).

4.1. Strengths and limitations

Whilst this study is limited by the fact that it reports on the activity of a single AHP at a single site, we hope that it has introduced a useful scheme for furthering the agenda for the development of AHPs who

both lead and help to deliver multi-centre research trials.

4.2. Future directions

Further work should include qualitative research studies exploring AHP experiences of both Associate PIs and PIs undertaking the Associate PI scheme in AHP-led trials, and the impact on the wider research/clinical team. Longitudinal studies are warranted to review the trajectory of Associate PIs and whether completing the scheme leads to long-term involvement and engagement in clinical research. The Associate PI scheme provides a model for training to support development of principal investigators that could be adopted in other countries, where this does not yet exist.

5. Conclusion

Building opportunities for AHPs to develop research skills is integral for fostering a research culture in healthcare settings. Uptake of the NIHR Associate PI scheme on an AHP-led trial (SIP SMART2) created an opportunity for AHPs to develop research skills and experience which corresponded well to Vitae RDF domains.

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Author contributions

All authors made substantial contributions to this article and approved the final manuscript for submission.

Florence Cook: Conceptualisation and design of the article, acquisition, analysis and interpretation of data, writing - original draft preparation, review and editing.

Irwin Nazareth: critically revising the draft manuscript, review and editing.

Roganie Govender: Conceptualisation and design of the article, acquisition, analysis and interpretation of data with Florence Cook, critically revising the draft manuscript, review and editing, supervision.

Conflict of interest

Roganie Govender is on the editorial board of *Advances in Communication and Swallowing.* She had no involvement in the peer review process of this paper.

Supplementary material

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References

Borkowski, D., McKinstry, C., Cotchett, M., Williams, C., & Haines, T. (2016). Research culture in allied health: A systematic review. *Australian Journal of Primary Health*, *22*(4), 294. https://doi.org/10.1071/PY15122

Bower, P., Brueton, V., Gamble, C., Treweek, S., Smith, C. T., Young, B., & Williamson, P. (2014). Interventions to improve recruitment and retention in clinical trials: A survey and workshop to assess current practice and future priorities. *Trials*, *15*, 399. https://doi.org/10.1186/1745-6215-15-399

Council for Allied Health Professions Research: About CAHPR. (2022). online. [https://cahpr.csp.org.uk/about-cahpr]

Dinneen, E., & Shaw, G. (2020). Life of PI (Associate). *BJU International*, *126*(6), 754–755. https://doi.org/10.1111/bju.15292

Evans, D. (2003). Hierarchy of evidence: A framework for ranking evidence evaluating healthcare interventions. *Journal of Clinical Nursing*, *12*(1), 77–84. https://doi.org/10.1046/j.1365-2702.2003.00662.x

Harris, J., Grafton, K., & Cooke, J. (2020). Developing a consolidated research framework for clinical allied health professionals practising in the UK. *BMC Health Services Research*, *20*(1), 852. https://doi.org/10.1186/s12913-020-05650-3

Health Research Authority. (2021). *Research Planning: Roles and Responsibilities*. online. https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/

Jepson, M., Lazaroo, M., Pathak, S., Blencowe, N., Collingwood, J., Clout, M., Toogood, G., Blazeby, J., & on behalf of the Sunflower Study Executive Group. (2021). Making large-scale surgical trials possible: Collaboration and the role of surgical trainees. *Trials*, *22*(1), 567. https://doi.org/10.1186/s13063-021-05536-7

Jones, D., & Keenan, A.-M. (2021). The rise and rise of NMAHPs in UK clinical research. *Future Healthcare Journal*, *8*(2), e195–e197. https://doi.org/10.7861/fhj.2021-0098

Matus, J., Walker, A., & Mickan, S. (2018). Research capacity building frameworks for allied health professionals – a systematic review. *BMC Health Services Research*, *18*(1), 716. https://doi.org/10.1186/s12913-018-3518-7

McGovern DPB. (2001). *Randomized controlled trials: Key topics in evidence based medicine.* (Vols 26–9). Oxford: BIOS Scientific Publishers.

McNiven, A., Boulton, M., Locock, L., & Hinton, L. (2021). Boundary spanning and identity work in the clinical research delivery workforce: A qualitative study of research nurses, midwives and allied health professionals in the National Health Service, United Kingdom. *Health Research Policy and Systems*, *19*(1), 74. https://doi.org/10.1186/s12961-021-00722-0

Medical Research Council. (2017). *2017 UK-Wide Survey of Clinical and Health Research Fellowships*. online

Medical Schools Council. (2017). *Survey of Medical Clinical Academic Staffing Levels 2017*. online.

National Health Service Workforce Statistics. (2022). online. https://digital.nhs.uk/data-and-information/publications/statistical/nhs-workforce-statistics

National Institute for Health and Care Research (NIHR). NIHR Associate Principal Investigator Scheme Virtual Launch Event. (2021). https://www.associatepilaunch.com

National Institute for Health and Care Research (NIHR). Associate Principal Investigator Scheme. (2022). Online. https://www.nihr.ac.uk/health-and-care-professionals/career-development/associate-principal-investigator-scheme.htm

Reeves, J., Denicolo, P., Metcalfe, J., & Roberts, J. (2012). *The Vitae Researcher Development Framework and Researcher Development Statement: Methodology and validation report*. Careers Research & Advisory Centre (CRAC) Ltd.

Slade, S. C., Philip, K., & Morris, M. E. (2018). Frameworks for embedding a research culture in allied health practice: A rapid review. *Health Research Policy and Systems*, *16*(1), 29. https://doi.org/10.1186/s12961-018-0304-2

Sully, B. G. O., Julious, S. A., & Nicholl, J. (2013). A reinvestigation of recruitment to randomised, controlled, multicenter trials: A review of trials funded by two UK funding agencies. *Trials*, *14*(1), 166. https://doi.org/10.1186/1745-6215-14-166

Vas, A., D'sa, P., Gokhale, S., Agarwal, T., Roberts, G. L., & Mohanty, K. (2021). Trainee Principal Investigator Could Improve Recruitment in Trauma Trials: Review of Literature and Experience From a Trauma Center. *Cureus*. https://doi.org/10.7759/cureus.18920

Vitae: Researcher Development Framework. Careers Research and Advisory Centre (CRAC) Limited. (2011). https://www.vitae.ac.uk/about-us

Wenke, R. J., Ward, E. C., Hickman, I., Hulcombe, J., Phillips, R., & Mickan, S. (2017). Allied health research positions: A qualitative evaluation of their impact. *Health Research Policy and Systems*, *15*(1), 6. https://doi.org/10.1186/s12961-016-0166-4

Wenke, R., & Mickan, S. (2016). The role and impact of research positions within health care settings in allied health: A systematic review. *BMC Health Services Research*, *16*(1), 355. https://doi.org/10.1186/s12913-016-1606-0