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CLINICAL PRACTICE

Recognising the importance of the research nurse and study coordinators in enhancing retention of people with haemophilia in clinical trials

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A survey of research nurses and study coordinators involved in haemophilia clinical trials highlights their role in enhancing retention and patient experience through individualised support, good communication, timely coordination and trusted relationships.

Introduction: For retention in clinical trials of investigational medical products (CTIMPS), the strategy and tactics to keep enrolled participants from discontinuing participation (dropouts) are important. Haemophilia trials often have extended follow-up and require motivated participants who commit for the duration of the study, which may be underestimated at initiation. Study discontinuation may lead to inconclusive results and prolonged trials. Research nurses (RNs) and study coordinators (SCs) play an important role in clinical trials and are considered the link between principal investigator and study participants. We discuss the importance of the RNs and SCs in retention of participants, the barriers and challenges to retention, and the interventions utilised

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to support it. **Methods:** We conducted a 12-question online survey at registration for a virtual research study update summit. The survey investigated the thoughts of RNs/SCs about retention in CTIMPS, their experiences and challenges, and interventions to prevent attrition. **Results:** Eighty-seven RNs and SCs from 24 countries (Asia, Australia, Europe, the Middle East and North America) participated. The majority (62/75 responses) reported having 1-5 or 6-10 clinical trial participants (46.6% and 36% respectively); the remainder reported 11-40 trial participants. The majority reported no or few participants dropping out of haemophilia clinical trials in the preceding three years (42.8% and 33.7% respectively). RNs/SCs believed participants dropped out because of 'loss of interest' (50%), 'study going on too long' (39%), 'too many visits' (virtual or at centre) (37.5%), 'visits are too time-consuming' (34%) and a 'lack of time' (32.8%). Over half of RNs/SCs believed 'dropouts' would be higher if they did not make extra efforts in retention. The top interventions to retain participants were: keeping an open dialogue, organising visits to fit participant schedules, discussing adverse events, understanding the protocol, and allowing participants time to ask questions. Retention is achieved through flexibility, timeliness, combining trial activities with routine care, shared decision making and effective communication, including via contemporary technology. **Conclusion:** This study investigating the retention role of RNs/SCs revealed low drop-out rates in haemophilia trials. RNs/SCs are able to offer flexibility to trial procedures by, for example, scheduling visits within trial timing 'windows' to support and facilitate individualised follow-up. Patient-centred care and attention, including trust, attitude and expectations, aid successful retention and trial outcomes. This often unrecognised role is important in supporting people with haemophilia in clinical trials to promote good study outcomes.

Keywords: *Retention; Clinical trials; Nurses, Haemophilia; Study coordinators*

Clinical trials of new investigational medicinal products (CTIMPs) form a key part of contemporary haemophilia management and include treatments that extend the circulating half-life of coagulation factors, mimic factor VIII cofactor activity, rebalance coagulation through targeting of natural anticoagulants, and induce production of endogenous factors with gene therapy [1]. Unlike common conditions, where CTIMPs enrol large numbers of participants into randomised controlled studies, in rare conditions such as haemophilia 'small' trials of a few hundred participants across multiple sites and regions are usual [2]. Globally, at the time of writing, there are almost 200 CTIMPs including people with haemophilia (PwH) in all age categories [3], with more than 20 studying gene therapy alone [4].

Due to the demand for study participants and the small number of PwH, it is imperative that those enrolled are retained for the study duration. The strategy and tactics used to keep enrolled participants from discontinuing (dropouts) are varied. Haemophilia trials with extended follow-up, often over many years, require motivated participants who can commit for the duration of the study, which can be underestimated or unknown at study initiation. Participant discontinuation may lead to inconclusive study results and prolonged CTIMPs.

The authors of this paper are members of the Novo Nordisk Haemophilia Support Committee (HSC). We are research nurses (RNs) and/or study coordinators (SCs) working on haemophilia CTIMPs sponsored by Novo Nordisk. We believe that PwH participating in both CTIMPs and observational studies are motivated and committed to remaining for the full study duration, resulting in valid conclusive results and the licensing of study drugs. This is beneficial to both the individual and the larger haemophilia community. We believe that RNs and SCs play an important role in clinical trials and that they are considered the link between principal investigators and study participants. However, there is limited published data to support this belief, and no publications that are haemophilia/bleeding disorder specific. We maintain retention through longstanding relationships with study participants, and flexibility in adapting trial procedures to enhance participant engagement and retention. Nurses also translate complex trial workflows into understandable language for patients before and/or during trials. The aim of this study and paper is to understand and discuss the importance of the RN and SC in the retention of PwH in haemophilia CTIMPs.

METHODS

The study consisted of two elements. The first, a systematic review to investigate the role of haemophilia RNs/SCs with regard to trial retention, will be published elsewhere. While there is published evidence about the general role of RNs/SCs in trial retention, we were

unable to find any publication that was haemophilia/bleeding disorder specific.

The second part of the study was an anonymous, online, non-validated survey completed by delegates registering to attend the virtual 2021 Novo Nordisk Global HSC summit for RNs and SCs conducting haemophilia CTIMPs (Appendix 1). The non-validated survey, comprising 12 questions, designed by the authors, collected basic demographic data and sought the delegates' thoughts and experiences, the challenges they encountered and the interventions they used to enhance retention and prevent attrition in clinical trials. Retention was defined as 'the strategy and tactics designed to keep participants enrolled in clinical trials from discontinuing participation' [5]. Survey participants were asked to complete the survey when registering for the Novo Nordisk Global HSC summit; consent was indicated by completion of the survey. Ethical approval was not required as this was a voluntary, anonymous non-patient study.

Responses to free text questions were recorded and coded into themes if relevant. The data were analysed using descriptive statistics.

RESULTS

In the systematic review four themes appeared that may be relevant to PwH. These are:

- Primary care – including maternal/child care [6], ageing [7] and nursing relationships [8]
- Under-represented groups – including Latino [9], Indian [10] and African American [11]
- Haematology/oncology – including venous thromboembolism [12], leukaemia [13], cancer [14] and stem cell transplant [15]
- Long-term conditions – including HIV [16] and children with hepatitis C [17].

These studies reported enhanced retention through dedicated RNs/SCs [10], patient contact, care and treatment [7] and support [12], shared experience and study insight [15], and processes [14].

The survey was initiated by 87 participants (35 RNs (40.2%), 38 SCs (43.7%) and 14 RNs/SCs (16.1%)) from 24 countries (Asia, Australia, Europe, the Middle East and North America) who responded to at least one question in the survey; not all responded to all questions (Table 1). Data presented show the number of responses per question; some had the option for multiple answers. Thirty-six RNs/SCs (58%) reported working in a haemophilia treatment centre vs. a clinical trials unit. Most (62/75 responses) reported having 1-5 or 6-10 clinical trial participants (46.6% and 36% respectively). The majority reported no or few participants dropping out of haemophilia clinical trials in the preceding three years (42.8% and 33.7% respectively), despite the impact of the COVID pandemic. Only 22/79 (28%) reported a COVID-related impact on CTIMP activity.

Forty of 72 participants who responded to the question on the perceived contribution of additional efforts on retention said they believed 'dropouts' would be higher if they did not make extra efforts or interventions to retain participants. The top five reasons RNs and SCs reported study participants dropping out of CTIMPs were 'loss of interest' (50%), 'study going on too long' (39%), 'too many visits' (virtual or at centre) (37.5%), 'visits are too time-consuming' (34%) and a 'lack of time' (32.8%).

When asked to identify what RNs/SCs did to keep participants trial compliant (and thus retained in study) 67 (77%) responded. The top five identified roles, from a drop-down list where multiple answers were possible, were: 'make the participant feel valued' (56, 83.5%), 'keeping an open dialogue/good relationship' (56, 83.5%), 'organise visits to fit with patient's schedule' (53/67 79.1%), 'ensure patient has understood study information' (47/67, 70.1%), and 'discuss any concerns about complaints/side effects reported by patient' (45/67, 67.1%). While motivational interviewing and goal setting did not score in the top five roles (featuring at sixth and eighth respectively) they were still important roles (see Table 1). The free text question revealed eight reasons for study participants dropping out of trials: 'travel' (5), 'study fatigue' (4), 'moved away' (2), 'time missed from school' (1), 'surgery outside of study protocol' (1), 'access to licensed product when on continuation study' (1), 'changed personal circumstances' (1).

Seventy-one RNs/SCs reported how they facilitated retention from a drop-down list where multiple answers were possible. The top reported interventions were: 'use technologies to communicate and remind' (41, 57.7%), 'provide updated study information' (32, 45%), 'ensure timely coordination of study visits' (30, 42.2%), 'coordinate all trial activities with routine care' (23, 32.3%), and enhance 'awareness education by retraining' (21, 29.5%). See Table 2.

Participants were asked if they felt they received adequate support from sponsors to improve study retention and 72 responses were received. Twenty-four (33.3%) 'completely agreed', 25 (34.7%) 'agreed a bit', 16 (22.2%) were 'not sure', 6 (0.08%) 'disagreed a bit', and 1 (0.01%) 'completely disagreed'.

Table 1. Participant demographics and beliefs on the retention of patients in clinical trials

	N (%)
Participant role (N=87*)	
Haemophilia Nurse	35 (40.2)
Haemophilia Study Coordinator	38 (43.7)
Both	14 (16.1)
Number of participants in clinical trials (N=75)	
1-5	35 (46.6)
6-10	27 (36.0)
11-20	7 (9.3)
21-30	3 (4.0)
31-40	1 (1.3)
41-50	2 (2.6)
Number of participants lost to clinical trials in preceding three years (N=70)	
None	33 (42.8)
1-5	26 (33.7)
6-10	9 (11.6)
11+	2 (0.02)
Do you think COVID-19 has impacted on patient participation in clinical trials? (N=79)	
Yes	22 (28%)
No	57 (72%)
Do you think your participants would leave studies prematurely if you didn't make extra efforts to retain them? (N=72)	
Yes	40 (55.5)
No	8 (11.1)
Not sure	24 (33.3)
Why do you think trial participants leave drug studies prematurely? (N=64; multiple answers possible, ranked highest to lowest)	
Loss of interest	32 (50.0)
The study goes on for too long	25 (39.0)
Too many visits (virtual or at centre)	24 (37.5)
Visits are too time-consuming	22 (34)
Lack of time	21 (32.8)
Too much data collection (diary, quality of life assessments, etc.)	19 (29.6)
Participation did not meet expectations	18 (28.1)
Too difficult to comply with protocol requirements long term	17 (26.5)
Timing of visits – would like evening hours/weekend – due to work/life situation	14 (21.8)
Using electronic diary	13 (20.3)
Too many blood tests	12 (18.75)
There are unnecessary visits (e.g. dispensing visits)	8 (12.5)
No compensation (travel)	7 (10.9)
No updates on study results	3 (4.6)

* Numbers of responses to each question varied

DISCUSSION

This study revealed that RNs/SCs believe there to be low drop-out rates in haemophilia clinical trials, although no published evidence to support this could be found. The RNs and SCs in this study are experienced in haemophilia care as well as research (data not shown but includes haemophilia research specific education and training provided by the study sponsor), and PwH appear to be well supported throughout the trial process. Well trained research staff with clear protocols for follow-up, and attentive, skilled nurses, 'knowledgeable in the area of research

Table 2. Roles of Research Nurses and Study Coordinators in clinical trials

	N (%)
What do you do to keep participants trial compliant? (N=67; multiple answers possible, ranked highest to lowest)	
Make the participant feel valued	56 (83.5)
Keeping an open dialogue/good relationship	56 (83.5)
Organise visits to fit with the patient's schedule	53 (79.1)
Ensure patient has understood study information	47 (70.1)
Discuss any concerns about complaints/side effects reported by patient	45 (67.1)
Allowing an environment for patient to ask questions	44 (65.6)
Discuss the diary data – make patients to know the data is important	39 (58.2)
Show blood results	36 (53.7)
Show global results and progress of the study	36 (53.7)
Updating on individual participants trial information e.g. adverse events	28 (41.7)
What do you do to facilitate retention? (N=71; multiple answers possible, ranked highest to lowest)	
Use technologies to communicate, support and remind (e.g. visits/diary entry) by text (SMS) email, etc.	41 (57.7)
Provide updated study information	32 (45.0)
Ensure timely coordination of study visit (patients do not have to wait)	30 (42.2)
Coordinate all trial activities with routine clinical care	23 (32.3)
Awareness education by re-training	21 (29.5)
Goal setting	20 (28.1)
Allow flexibility to accommodate participants' needs	18 (25.3)
Motivational interviewing	18 (25.3)
Shared decision making	17 (23.9)
Promote peer-to-peer support	13 (18.3)

who are readily available for their patients', are known to enhance study retention [18,19,20]. The RNs and SCs in our study are able to support trial participants through encouragement, respect, education and communication, maintaining their confidence and a joint wish to succeed.

Additional efforts are made by RNs/SCs to retain study participants in clinical trials. Participants in our study rated doing more to 'make the participant feel valued' and 'keeping an open dialogue/good relationship with the participant' (56/67, 83.5%) as their highest priorities in retention. Penkofer et al. [21] describe knowing participants' characteristics as being a key motivator in the 'research relationship', pointing to the importance of 'gaining and maintaining participant's trust, demonstrating a sense of caring, respecting and valuing the contribution of the individual to the interpersonal relationship'. Maintaining the sense of value felt by study participants is enhanced by keeping an open dialogue/good relationship with them as individuals. Among the staff members involved in CTIMPs, RNs/SCs have the most direct contact and interaction with study participants [9], supporting ongoing collaboration, promoting privacy of health information, and providing emotional support, all of which are critical to retention [22]. This is also important when it comes to identifying barriers to participation in clinical trials. Morse [23] suggests that clinicians involved in day-to-day care of patient populations are both well placed and successful in identifying barriers to research participation, and able to find solutions that enhance retention.

The majority (53/67, 79.1%) of RNs/SCs participating in this study reported organising study visits to fit with patients' schedules through coordinating visits in a timely way, with routine clinical care where possible, and by flexibility in appointment scheduling, including early morning/late evening appointments. This level of flexibility has been shown by Roy et al. [17] to enhance trial retention by keeping study participants and their family members 'engaged, involved and motivated throughout long trials'. Gul and Ali [18] also report that flexible hours and convenient places for trial activities enhance retention. Within haemophilia care this could include trial activities being undertaken within the haemophilia centre, by trusted haemophilia staff, allowing non-trial activities such as physiotherapy assessments or non-trial sibling appointments to take place at the same time.

Ensuring trial compliance (and hence retention) is another key aspect of the RN/SC role. Leighton [19] identified the importance of how well a study is understood and valued in individual participants' willingness to remain involved. It is also recognised that RNs have 'high research knowledge' and 'confidence using teach-back', whereby information is discussed with study participants who are then asked to teach back what they have learnt to the nurse [24]. In our study 47/67 (70.1%) reported 'ensuring patient has understood study information' as a central aspect of participant retention, and providing updated study information was reported as important by 32 (45%). Teach-back is particularly important in new and evolving therapies in haemophilia, such as non-factor replacement therapy and gene therapy, where trial participants may experience unexpected side effects of treatment [25].

In a study by Berger et al. [26], successful retention 'depended on the value that site personnel placed on symptom management'. In our study, over two thirds (67.1%) of RNs/SCs rated discussion of concerns and complaints of side effects reported by patients as a key role in ensuring that trial participants remained compliant with and retained in studies. Roy et al. [17] suggest that ongoing education and support reduces family stress, contributing to high retention rates despite high adverse events. While motivational interviewing and goal setting (ranked sixth and eighth in our study) are not easily adapted into protocols for CTIMPS, Rosal et al. [9] suggest that 'strategies of maintaining rapport, understanding motivation to participate, problem solving of challenges and logistics' are key aspects for patient support provided by trial staff. Support provided through ongoing meaningful relationships, patient education and effective communication have all been identified as important factors when helping to manage patient expectations [27].

Supporting trial participants goes beyond face-to-face, in-person engagement. The use of technology to communicate and remind participants scored highly in our study, with 57.7% of respondents saying they used technology (telephone calls, emails and text messaging) to keep in touch with participants between planned visits. Telephone calls between visits have been shown to enhance retention [27], and to support dose monitoring [24] and study compliance [17].

Loss of study understanding by participants may be a barrier to retention, particularly if studies are lengthy. 'Awareness education by retraining' was identified as the fifth most important area of focus by RNs/SCs in our study (21/71), 29.5%). Information booklets and counselling sessions to 'inform', 'remind', 'involve' and 'support' [12], in addition to ongoing education [17], have been reported as being successful tools to maintain trial retention. The HSC committee members and Novo Nordisk have developed various study-specific, age-relevant, patient education, training and support materials for uses by RNs/SCs with study participants, translated into languages appropriate to their setting. These are frequently used but have not, as yet, been evaluated. This is a future research opportunity. Alongside these materials, the experience of HSC committee members means it is well placed to offer training to HCPs, including primary investigators (PIs) as well as RNs/SCs involved in clinical trials, to support and enhance retention activities.

Limitations

This is a small study of RNs/SCs who were attending a virtual research summit. As such, they may represent different views to those of RNs/SCs who did not attend. We have reported our finding of the views of RNs/SC, but these may not reflect the views of PwH. Further study is required to seek their views.

CONCLUSION

This study, investigating the importance of RNs/SCs on retention in clinical trials, reveals a perceived low drop-out rate in haemophilia trials, confirming the views of the Novo Nordisk Haemophilia Support Committee. RNs/SCs are able, where possible within the confines of trial protocols, to adapt trial procedures through, for example, flexible timing and combining appointments to support and facilitate individual follow-up. These often unrecognised activities enhance retention and the experience of PwH in CTIMPs through individualised patient-centred support, good communication, timely coordination of trial activities and ongoing trusting relationships within the multidisciplinary team (including PI, study monitors and pharmacy) facilitating trials. The tools available for RNs/SCs that support peer-to-peer learning within haemophilia clinical trials research help to maintain retention and, through engaged RNs/SCs, extend to trials beyond haemophilia and other bleeding disorders.

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Disclosures

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APPENDIX

Non-validated survey completed by delegate of the HSC 2021 summit

QUESTION	ANSWER
Which country are you from?	Drop-down list
Are you a	Tick box: ◯ Haemophilia nurse; ◯ Haemophilia study coordinator; ◯ Both
Where do you mostly work?	Tick box: ◯ Haemophilia centre; ◯ Clinical trials unit
Do you think retention in haemophilia clinical drug studies is an issue?	Tick box: ◯ Yes; ◯ No
How many participants do you have in haemophilia drug trials at this moment?	Tick box: ◯ 1-5; ◯ 6-10; ◯ 11-20; ◯ 21-30; ◯ 31-40; ◯ 41-50
How many participants have dropped out of haemophilia drug trials at your centre due to retention issues within the past 3 years?	Tick box: ◯ 0; ◯ 1-5; ◯ 5-10; ◯ More
Please indicate participants' reasons for dropping out of the trial	Free text:
Why do you think trial participants leave drug studies prematurely? (Please tick all that apply)	Tick box: (multiple answers possible) ◯ Participation did not meet expectations ◯ Loss of interest/motivation ◯ The study goes on for too long ◯ Lack of time ◯ Too many visits (virtual or at centre) ◯ Visits are too time consuming ◯ There are unnecessary visits (e.g. dispensing visits) ◯ Timing of visits – would like evening hours/weekend – due to work/life situation ◯ Too much data collection (diary, quality of life assessments, etc.) ◯ Using electronic diary ◯ Too difficult to comply with protocol requirements long term ◯ Too many blood tests ◯ No compensation (travel) ◯ No updates on study results
Do you think COVID-19 has impacted on patient participation in clinical trials?	Tick box: ◯ Yes; ◯ No

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QUESTION	ANSWER
What do you do to keep participants trial compliant? (Please tick all that apply)	Tick box: (multiple answers possible) ◯ Show blood results ◯ Show global results and progress of the study ◯ Make the participant feel valued ◯ Keeping an open dialogue/good relationship ◯ Ensure patient has understood study information ◯ Allowing an environment for patient to ask questions ◯ Organise visits to fit with the patient's schedule ◯ Discuss the diary data – make patients know the data is important ◯ Discuss any concerns about complaints/side effects reported by patient ◯ Updating on individual participants trial information e.g. AEs ◯ Updating on global SAEs and reconsenting
What do you do to facilitate retention? (Please tick all that apply)	Tick box: (multiple answers possible) ◯ Motivational interviewing ◯ Shared decision-making ◯ Goal setting ◯ Use technologies to communicate, support and remind (e.g. visits/diary entry) by text (SMS) e-mail, etc. ◯ Promote peer-to-peer support ◯ Ensure timely coordination of study visit (patients do not have to wait) ◯ Allow flexibility to accommodate participants' needs ◯ Provide updated study information ◯ Coordinate all trial activities with routine clinical care ◯ Awareness education by re-training
Do you think your participants would leave studies prematurely if you didn't make extra efforts to retain them?	Tick box: ◯ Yes; ◯ No; ◯ Not sure
Do you think you get enough support from sponsors to improve study retention?	Five-point Likert scale: ◯ I completely agree; ◯ I agree a bit; ◯ I am not sure; ◯ I disagree a bit; ◯ I completely disagree