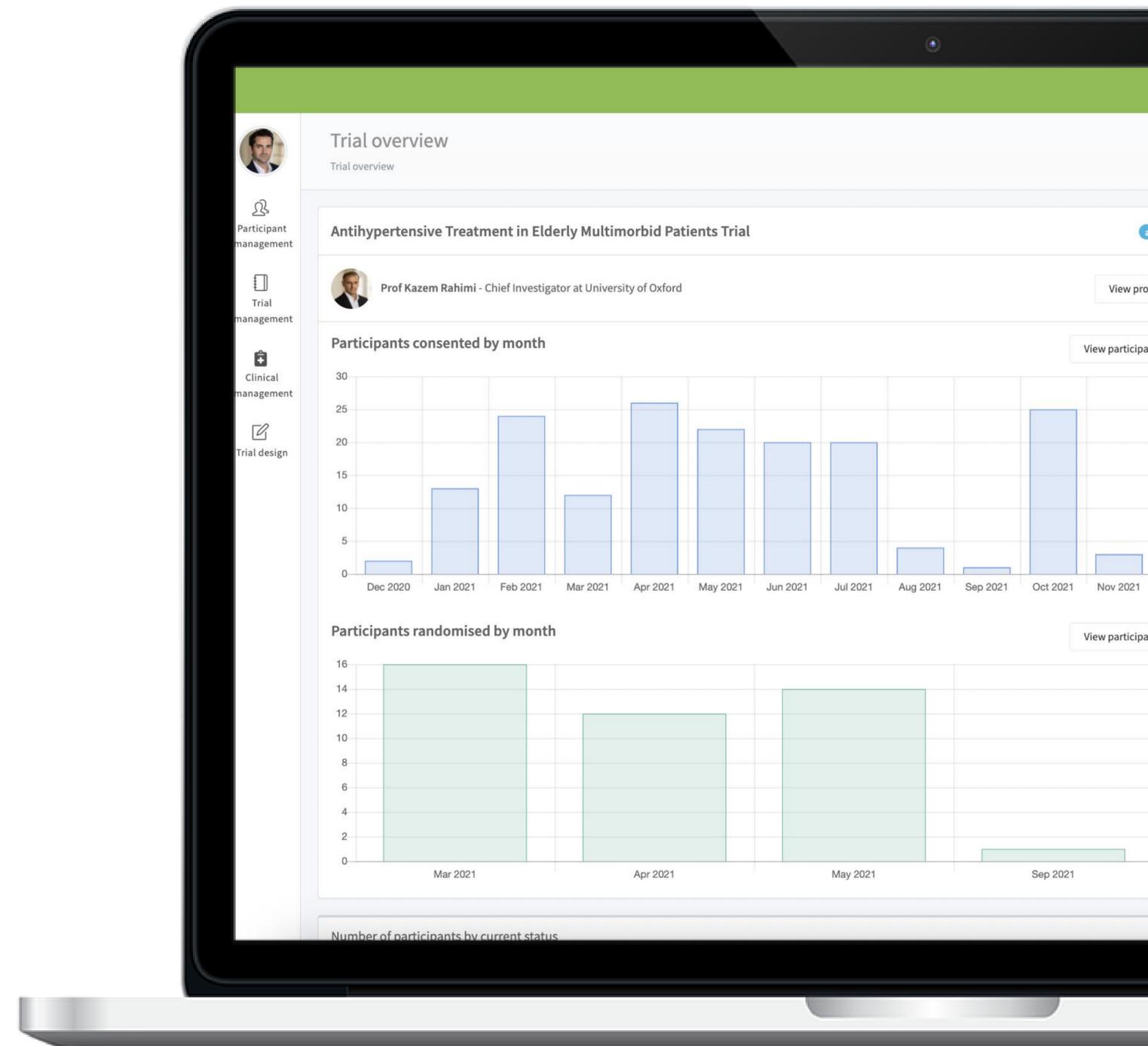


The problem

- ⊗ Existing solutions to run clinical trials are **inefficient** because they are:
 1. **Expensive** (due to large admin and monitoring costs)
 2. **Time-consuming** (e.g. delayed start-up, labour-intensive tasks)
 3. **Rigid** (they don't allow much tailoring to the clinical trial needs)
- ⊗ Complexity in clinical trials has been growing over the last 20 years

Zeesta: A flexible cloud-based Unified Clinical Trials Management System

- ✔ Drag & drop-like configuration
- ✔ FDA part 11 compliance
- ✔ Secure and compliant with GDPR and HIPAA
- ✔ EHR and other third-party integrations
- ✔ Full or partial virtualisation





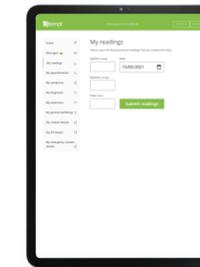
Antihypertensive Treatment Evaluation in Multimorbidity and Polypharmacy Trial.

- Randomized trial
- Drug intervention
- 230 participants
- Fully virtual
- 1 study site
- 4 researchers
- 2 years
- 50 CRFs



Trial Management Platform

- | | |
|-------------------------|----------------------------|
| Trial design | EDC |
| CRFs design | Eligibility |
| Recruitment management | Letter templates |
| Participants management | Trial Master File |
| Randomization | Notifications |
| Stratification | Audit |
| Diary and alerts | Team management |
| Dashboard | User roles and permissions |
| Reports | Inventory |
| Data export | Database lock |



Participant Portal

- Pre-eligibility
- eConsent
- Readings
- Questionnaires
- Messaging



Integrations

- Pharmacy
- EHRs
- SMS services
- Mailing



Messsages

Participants / Participant AT-UN0350 / Messages

Compose

Participant management

Trial management

Trial design

- Messages 43
- Calls 1
- Notes 7
- Letters 4

10 messages per page

Search

- Message from the participant To do
From participant AT-UN0350 to the ATEMPT team

30 May 2022 16:17
- Message from the participant To do
From participant AT-UN0350 to the ATEMPT team

30 May 2022 16:13
- Reply**
From Jeannette Majert to participant AT-UN0350

19 May 2022 11:25
- Message from the participant Completed Jeannette Majert
From participant AT-UN0350 to the ATEMPT team

16 May 2022 13:26
- Reply
From Jeannette Majert to participant AT-UN0350

13 May 2022 08:54
- Message from the participant Completed Jeannette Majert
From participant AT-UN0350 to the ATEMPT team

12 May 2022 11:23
- Blood results and prescription for Bisoprolol
From Jeannette Majert to participant AT-UN0350

11 May 2022 12:48



Inventory

Inventory

Any device type | Any status | Any participant

Register new device



Participant management

Trial management

Monitoring

Copy | CSV | Excel | Print

Search all columns:

| Device code | Device type | Status | Participant | Registered on | |
|-------------------------------|----------------------------|------------|-------------------------|---------------|--|
| A&D -0001 | A&D blood pressure monitor | Allocated | PH-OX18 | 11 May 2022 | View Change status |
| A&D -0002 | A&D blood pressure monitor | Registered | | 15 May 2022 | View Change status |
| A&D -0003 | A&D blood pressure monitor | Registered | | 15 May 2022 | View Change status |
| PULS-001 | Pulse Oximeter | Allocated | PH-OX22 | 16 Aug 2022 | View Change status |
| PULS-002 | Pulse Oximeter | Registered | | 28 Feb 2023 | View Change status |

Showing 1 to 5 of 5 entries

Participant management

Trial management

Monitoring

Data monitoring

Data monitoring

Any participant

Data query

Pending

Show 10 entries

Search:

| ID alert | Safety alert type | Title | Participant | Status | Created time | |
|----------|-------------------|--|-------------|---------|-------------------|---|
| 780 | Data query | Data query on Serious adverse event assessment CRF | TEST64 | Pending | 15 Feb 2023 09:52 | 🔍 |
| 766 | Data query | Data query on Blood and ECG procedures CRF | TEST63 | Pending | 14 Feb 2023 12:23 | 🔍 |
| 399 | Data query | Data query on Serious adverse event assessment CRF | PH-OX20 | Pending | 15 Aug 2022 13:55 | 🔍 |

Showing 1 to 3 of 3 entries

-  Participant management
-  Trial management
-  Monitoring

Database locks

Database locks

| Reference | Type |
|-----------------------------|------|
| Number of database locks: 0 | |

Lock database ▾

Hard database lock

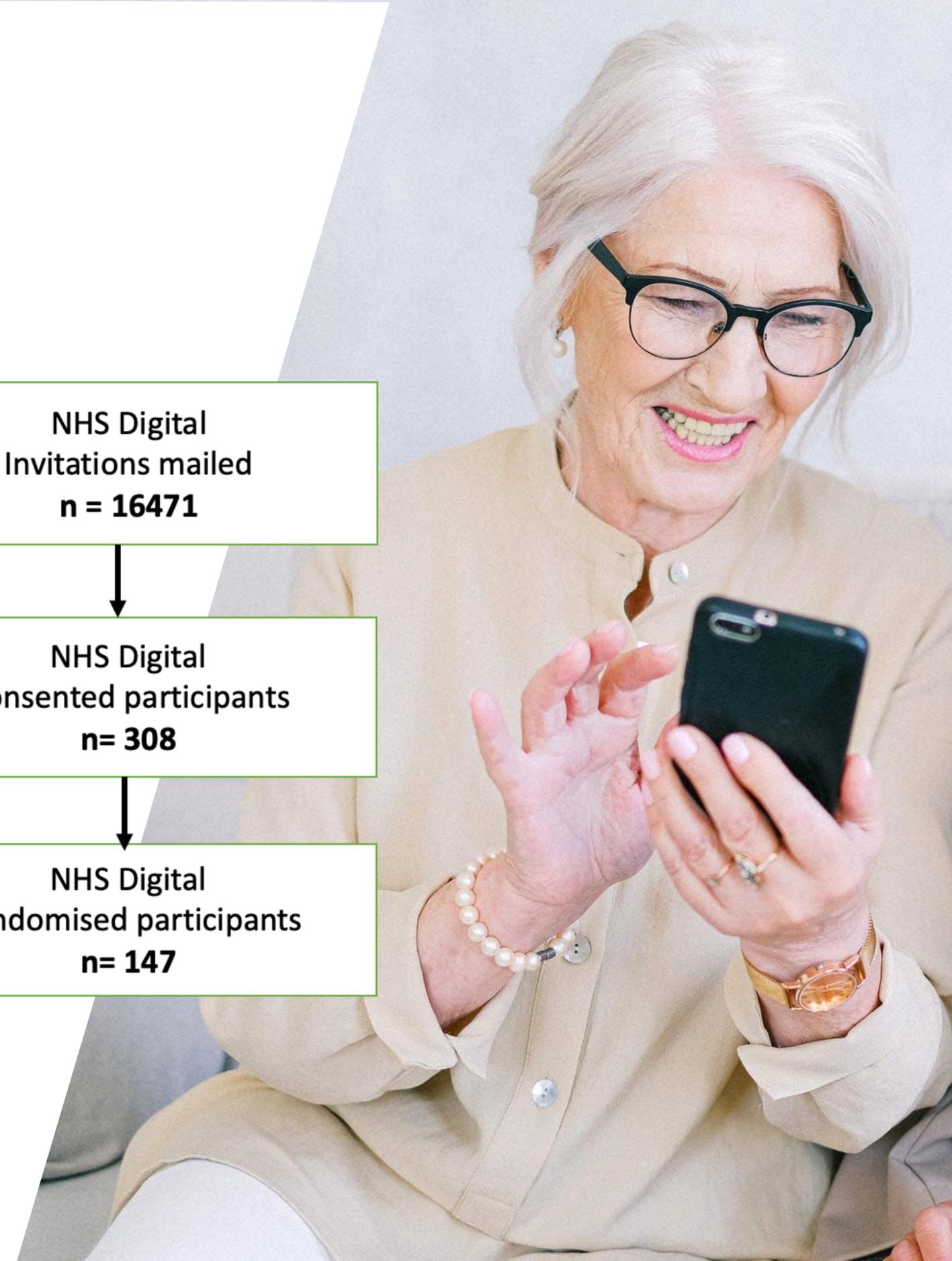
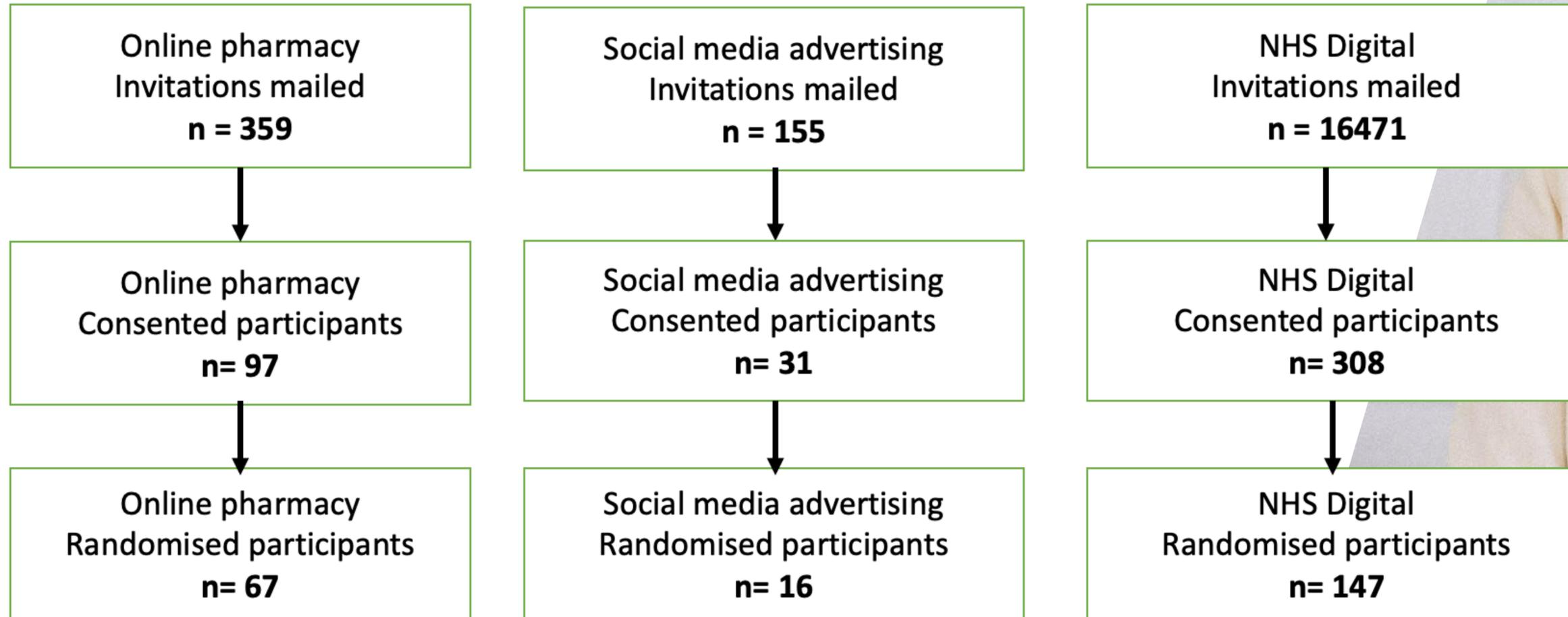


The hard lock will disable data entry and all user accounts.

Justification

Your password

Recruitment routes tested





Feedback from participants

Would you be willing to be considered for the next phase ATEMPT trial?

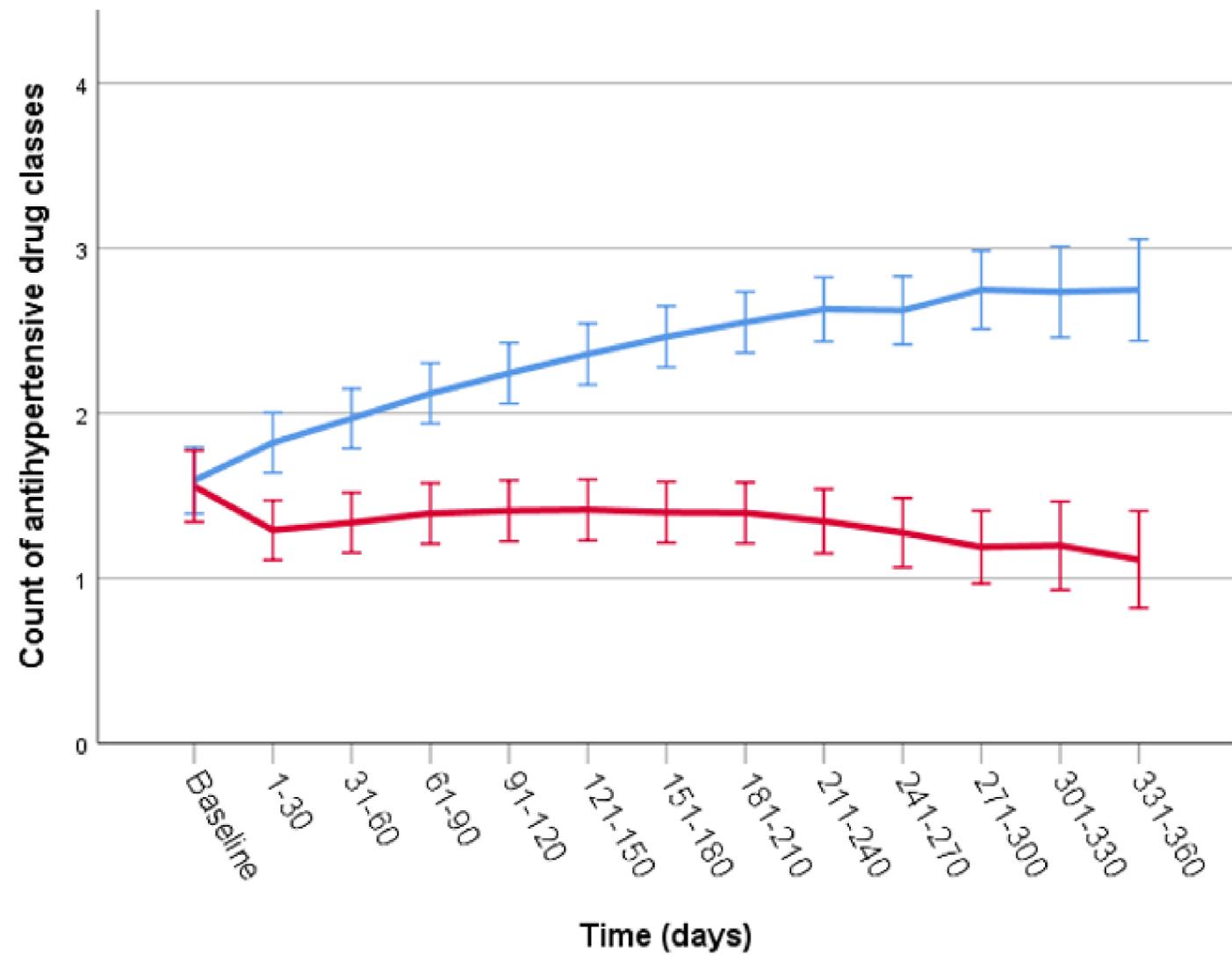
100% Very satisfied

How easy did you find the trial registration process on the study web portal?

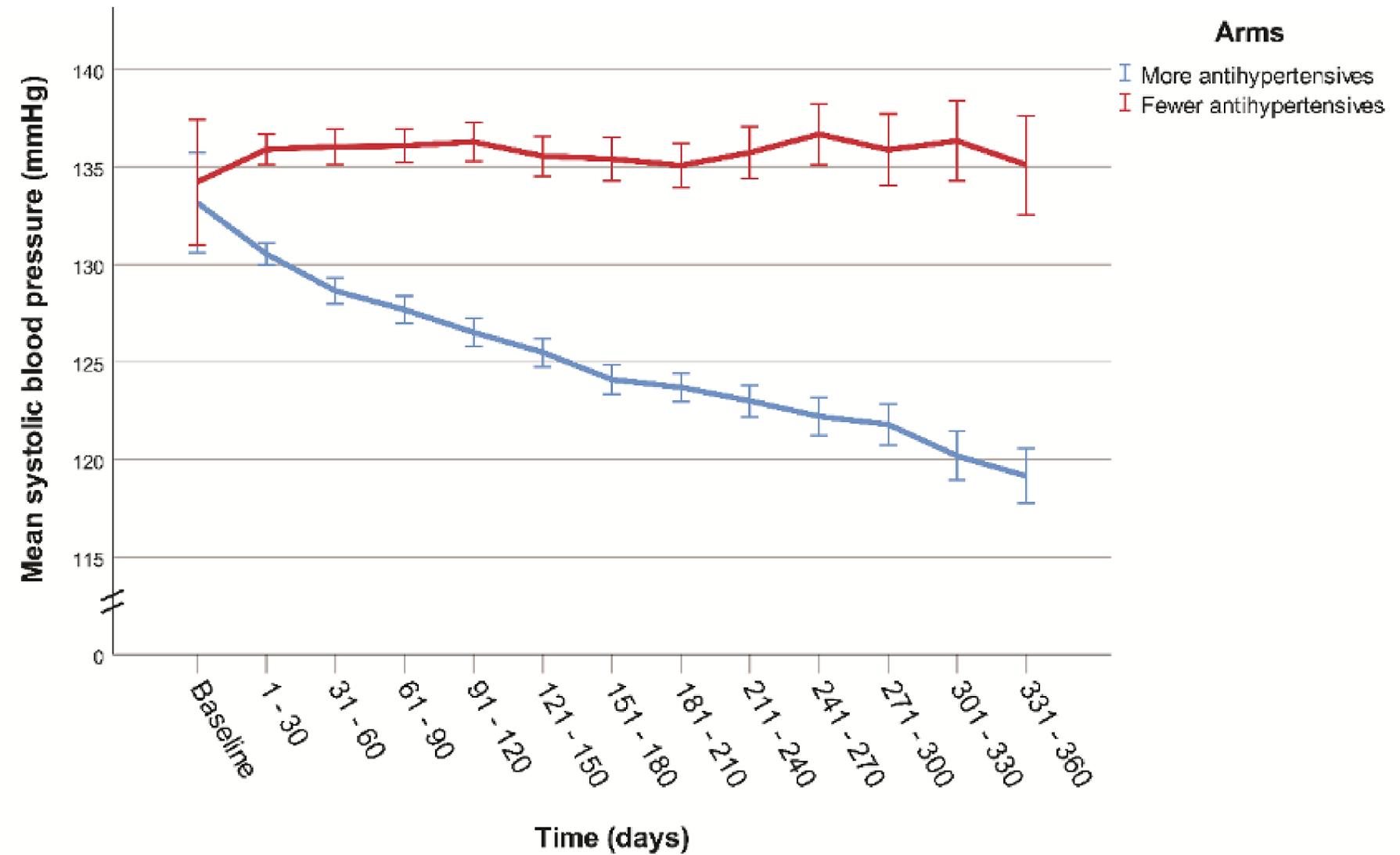
92% Very satisfied

Results

Increase in number of prescribed antihypertensives



Corresponding drop in blood pressure



Results: Physical and cognitive functioning

Health-related quality of life at 3-monthly intervals.

| | Intervention (n=125) | | | | | | P-Value _a | Control (n=104) | | | | | |
|---------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-------------|----------------------|
| | Mean [SD]/ median [IQR] | | | | | | | Mean [SD]/ median [IQR] | | | | | |
| | Baseline | Month 3 | Month 6 | Month 9 | Month 12 | | | Baseline | Month 3 | Month 6 | Month 9 | Month 12 | P-Value _a |
| EQ-5D-5L | | | | | | | | | | | | | |
| Health state index score | 0.7(0.1)/0.7(0.1) | 0.8(0.1)/0.8(0.1) | 0.7(0.1)/0.7(0.1) | 0.7(0.1)/0.7(0.1) | 0.7(0.1)/0.7(0.1) | 0.82 | 0.7(0.1)/0.7(0.1) | 0.8(0.1)/0.8(0.1) | 0.7(0.1)/0.7(0.2) | 0.7(0.1)/0.7(0.1) | 0.7(0.1)/0.7(0.2) | 0.84 | |
| Subscale: | | | | | | | | | | | | | |
| Mobility | 1.6(0.9)/1(1) | 1.5(0.7)/1(1) | 1.7(0.9)/1.9(1) | 1.6(0.8)/1(1) | 2.0(1.0)/2(1.7) | 0.68 | 1.8(0.8)/2(1.2) | 1.4(0.5)/1(1) | 1.9(0.8)/2(2) | 1.8(0.9)/2(1) | 2.0(0.9)/2(2) | 0.89 | |
| Self-care | 1.1(0.4)/1(0) | 1.2(0.4)/1(0) | 1.2(0.5)/1(0) | 1.1(0.5)/1(0) | 1.2(0.4)/1(0) | 0.92 | 1.1(0.4)/1(0) | 1.1(0.3)/1(0) | 1.2(0.4)/1(0) | 1.2(0.5)/1(0) | 1.3(0.6)/1(0.6) | 0.90 | |
| Usual activities | 1.5(0.7)/1(1) | 1.5(0.5)/1.5(1) | 1.6(0.7)/1(1) | 1.6(0.7)/1(1) | 1.9(1.0)/2(2) | 0.87 | 1.6(0.8)/1(1) | 1.5(0.6)/1.5(1) | 1.8(0.8)/2(1) | 1.6(0.8)/1(1) | 1.9(0.9)/2(1.6) | 0.78 | |
| Pain/discomfort | 1.9(0.8)/2(1) | 1.7(0.8)/1.5(1) | 2.0(0.7)/2(0) | 1.9(0.7)/2(1) | 2.3(0.7)/2(1) | 0.54 | 2.0(0.8)/2(2) | 1.7(0.8)/1.7(1.2) | 2.1(0.7)/2(1) | 1.9(0.8)/2(1) | 2.0(0.7)/2(1.2) | 0.70 | |
| Anxiety/depression | 1.3(0.6)/1(1) | 1.2(0.4)/1(0) | 1.2(0.5)/1(0.1) | 1.3(0.5)/1(1) | 1.4(0.6)/1(1) | 0.87 | 1.3(0.5)/1(1) | 1.3(0.8)/1(0) | 1.6(0.7)/1.5(1) | 1.3(0.5)/1(1) | 1.5(0.7)/1(1) | 0.78 | |

Results: Physical and cognitive functioning

Cognitive function at 3-monthly intervals.

| | Intervention (n= 126) | | | | | | P-Value ^a | Control (n= 103) | | | | | |
|--------------------------------------|-------------------------|------------------------|------------------------|------------------------|------------------------|-------------|------------------------|--------------------------|--------------------------|------------------------|----------------------------|-----------------|----------------------|
| | Mean [SD]/ median [IQR] | | | | | | | Mean [SD]/ median [IQR] | | | | | |
| | Baseline (n=126) | Month 3 (n=28) | Month 6 (n=90) | Month 9 (n=86) | Month 12 (n=44) | | | Baseline (103) | Month 3 (n=27) | Month 6 (n=70) | Month 9 (n=73) | Month 12 (n=34) | P-Value ^a |
| Overall T-MoCA score | 19.7(1.8)/20(2) | 19.5(1.7)/20(3) | 19.8(2.0)/20(3) | 20.1(1.9)/20(3) | 20.8(1.4)/21(2) | 0.87 | 19.3(2.2)/20(3) | 18.9(3.8)/20(2.5) | 19.4(2.2)/20(2.8) | 20.3(1.9)/21(3) | 19.5(3.0)/20.7(3.1) | 0.90 | |
| Cognitive impairment ^{b, c} | 28 (22.2) | 8 (28.6) | 23(25.6) | 17(19.8) | 3 (6.8) | <0.001 | 30 (29.1) | 7 (25.9) | 19(27.1) | 13 (17.8) | 9(26.5) | <0.001 | |
| Subscales: | | | | | | | | | | | | | |
| Digit span | 1.9(0.2)/2(0) | 2(0)/2(0) | 1.9(0.2)/2(0) | 1.9(0.2)/2(0) | 1.9(0.1)/2(0) | 0.75 | 1.9(0.2)/2(0) | 1.9(0.2)/2(0) | 1.9(0.2)/2(0) | 1.9(0.3)/2(0) | 1.8(0.4)/2(0) | 0.71 | |
| Attention | 5.3(0.9)/6(1) | 5.5 (0.7)/6(1) | 5.3(0.8)/6(1) | 5.4(0.6)/6(1) | 5.6(0.6)/6(0.6) | 0.91 | 5.2(0.9)/6(1) | 5.4(1.1)/6(0.5) | 5.4(0.8)/6(1) | 5.4(0.8)/6(1) | 5.2(1.2)/6(1) | 0.84 | |
| Repetition | 1.5(0.5)/2(1) | 1.6(0.5)/2(1) | 1.7(0.4)/2(1) | 1.7(0.4)/2(0.3) | 1.8(0.4)/2(0) | 0.84 | 1.5(0.5)/2(1) | 1.6(0.5)/2(1) | 1.5(0.6)/2(1) | 1.7(0.5)/2(0.5) | 1.6(0.5)/2(0.8) | 0.89 | |
| Verbal fluency | 0.7(0.4)/1(0) | 0.8(0.3)/1(0) | 0.7(0.4)/1(0) | 0.8(0.3)/1(0) | 0.8(0.3)/1(0) | 0.80 | 0.7(0.4)/1(1) | 0.7(0.4)/1(0.5) | 0.6(0.4)/1(1) | 0.7(0.4)/1(0.5) | 0.6(0.4)/1(1) | 0.92 | |
| Abstraction | 1.9(0.2)/2(0) | 1.8(0.3)/2(0) | 1.9 (0.2)/2(0) | 1.9 (0.2)/2(0) | 1.9(0.2)/2(0) | 0.95 | 1.8(0.3)/2(0) | 1.7(0.6)/2(0) | 1.8 (0.3)/2(0) | 1.9 (0.2)/2(0) | 1.8(0.3)/2(0) | 0.90 | |
| Recall | 4.1(1.1)/5(1) | 4.1(0.9)/4(2) | 4.0 (1.3)/4.7(2) | 4.2(1.1)/5(1) | 4.5(0.7)/5(1) | 0.90 | 3.9(1.4)/5(2) | 3.7(1.7)/4(2) | 3.9(1.4)/4(1.5) | 4.3(1.1)/5(1) | 4.3(0.9)/5(1) | 0.95 | |
| Orientation | 5.7(0.5)/6(0) | 5.3(0.8)/6(1) | 5.7 (0.4)/6(0.5) | 5.7 (0.4)/6(0.5) | 5.7(0.5)/6(0.1) | 0.95 | 5.5(0.6)/6(1) | 5.2(1.1)/6(1) | 5.6(0.5)/6(1) | 5.7(0.4)/6(0) | 5.4(0.8)/6(1) | 0.87 | |

a. Test for temporal trend; b. A score below 19 on the modified telephone interview for cognitive status (T-MoCA) categorised as cognitively impaired; c. n (%)

Lessons learned

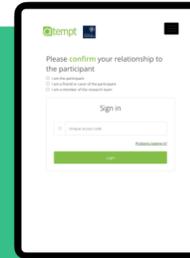
- ✔ Digitisation and automation can lead to substantial efficiency in clinical trials
- ✔ Decentralised approaches work even in older multi morbid patients
- ✘ Conventional approaches to measurement of physical and cognitive functioning reach their limitation

Flexible end-to-end clinical trial workflow management

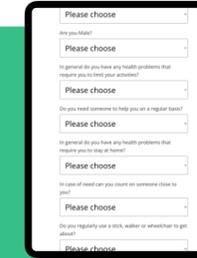
Tailored approach that minimises operational and regulatory risks

1 to 2 weeks

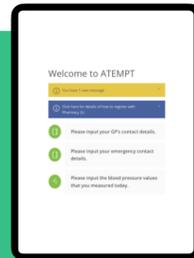
From the Kick-off meeting to a ready-to-use study environment



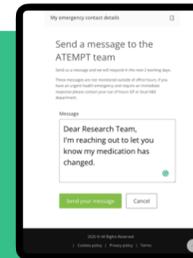
Recruitment via Referral, Social Media or Clinic



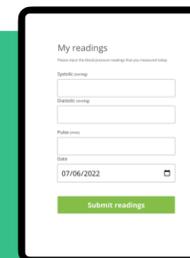
Automated eligibility



Notifications and reminders



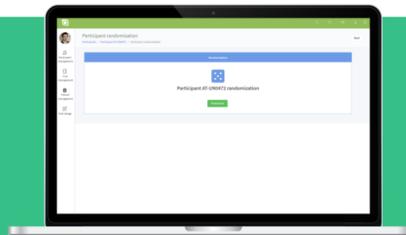
Direct communication (messaging, televisits)



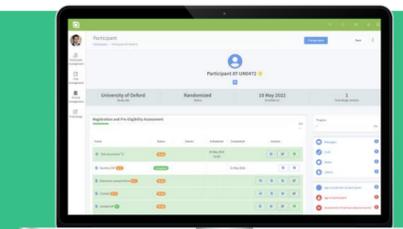
eCOA, ePRO, eDiary, Image capture, questionnaires



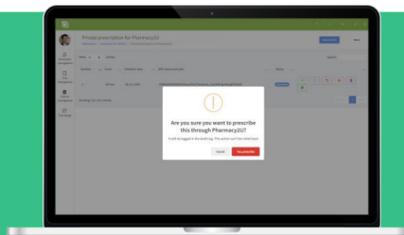
eConsent



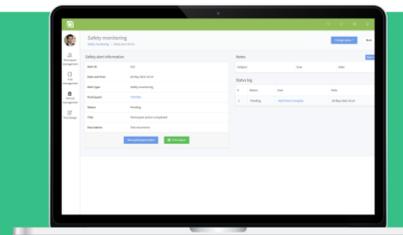
Randomisation and stratification



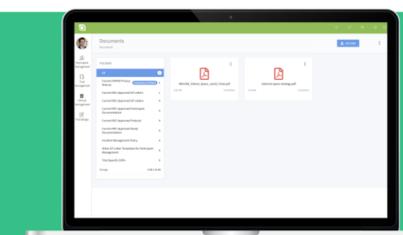
Tasks automation



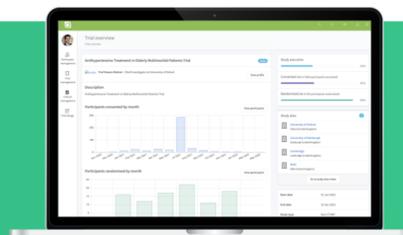
Link with data service providers



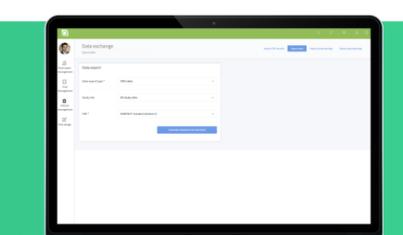
Safety and Data Quality monitoring



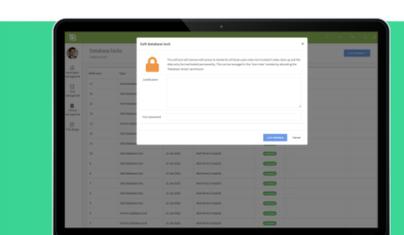
Sites, users, document management



Dashboard and reports



Data export



Database integration

Zeeesta

Simplify and shorten execution time of clinical trials

kazem.rahimi@wrh.ox.ac.uk