Investigating a structured diagnostic pathway for chronic breathlessness in primary care: a mixed methods feasibility cluster randomised controlled trial (cRCT).

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Background

Breathlessness is a common and distressing symptom which negatively affects physical function, quality of life and survival

There are known delays in investigations and diagnosis for conditions such as Chronic Obstructive Pulmonary Disease (COPD) and Heart failure which commonly present with chronic breathlessness

Overarching Research Question: Would a symptom-based pathway for breathlessness with early investigations lead to early diagnosis and better outcomes for patients?
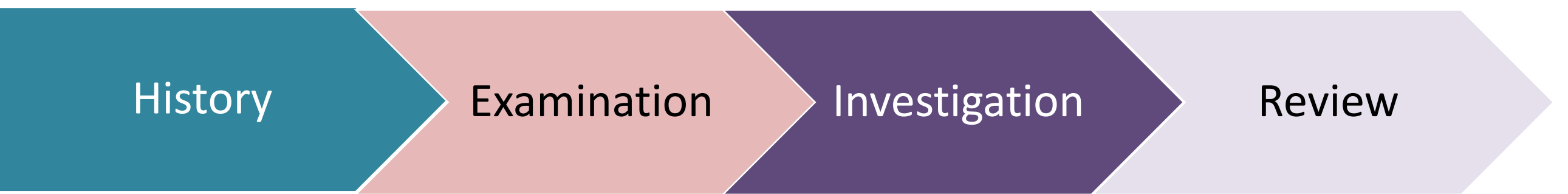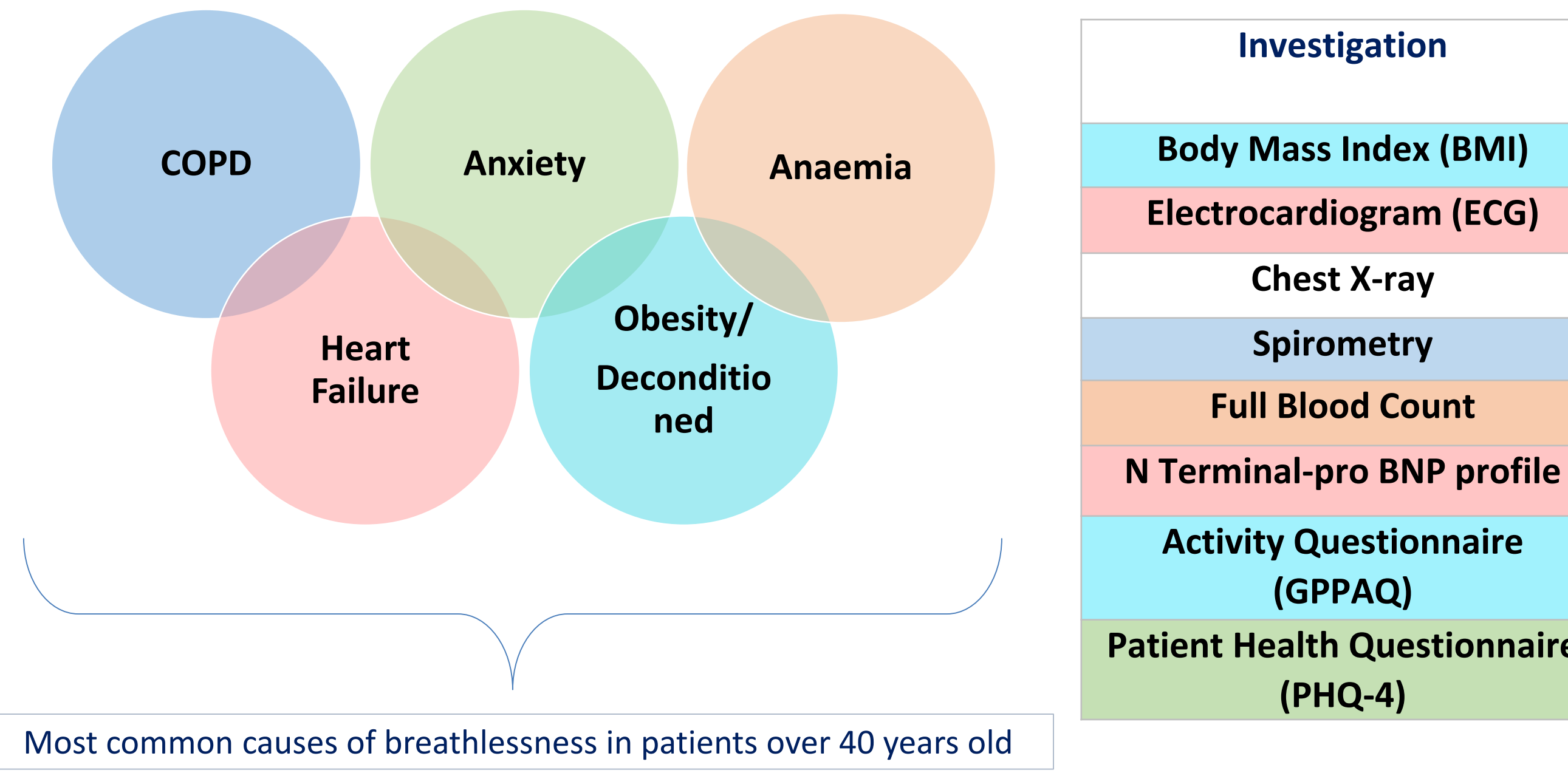
Aim

To conduct a feasibility study of a future cluster randomised controlled trial (cRCT) to:
1) assess recruitment and retention rate
2) explore patient reported outcomes for a primary outcome
3) explore current care through the experiences of clinicians and adults presenting with chronic breathlessness awaiting a diagnosis.

Methods

➤ Patients were eligible if they were presenting with chronic breathlessness for the first time, over 40 years old and without a pre-existing diagnosis for their symptoms.
➤ Ten General Practitioner (GP) practices in the UK, were cluster randomised to either a structured diagnostic pathway (intervention) including a panel of early investigations (Figure 1), or usual care.
➤ Outcome measures relating to dyspnoea, mental health and health-related quality of life (HRQoL) were collected at baseline, six and twelve months; Multidimensional Dyspnoea Profile (MDP), Dyspnoea-12, Chronic Heart Questionnaire (CHQ), Hospital Anxiety and Depression score (HADS), EuroQol 5 Dimension 5-Level (EQ5D-5L).
➤ Semi-structured interviews were completed exploring experiences of breathlessness diagnosis; transcripts were evaluated using thematic analysis supported by NVivo software.

Figure 1. Intervention – A structured diagnostic pathway

including early investigations to diagnose or exclude five common causes of chronic breathlessness in people over age of 40 years.

COPD, Anxiety, Anaemia, Heart Failure, Obesity/Deconditioned

Most common causes of breathlessness in patients over 40 years old

Investigation
Body Mass Index (BMI)
Electrocardiogram (ECG)
Chest X-ray
Spirometry
Full Blood Count
N Terminal-pro BNP profile
Activity Questionnaire (GPPAQ)
Patient Health Questionnaire (PHQ-4)

History → Examination → Investigation → Review

Results

➤ Figure 2 shows the participant flow diagram.
➤ 48 patients (65% female, mean age 66 [SD: 11] years, mean BMI 31.2 [SD: 6.5], Medical Research Council (MRC) dyspnoea scale median 2 [IQR: 2-3]) were recruited between Nov'19 to Feb'21.
➤ Recruitment rate = 23% (51/220), Retention rate = 85% (41/48)
➤ Within three months of presentation to primary care, the intervention group experienced a median (IQR) of 6 (5-7) tests versus 3 (3-5) tests in the usual care group.
➤ At 12 months:
  • 11 (44%) patients in the Intervention group had a coded diagnoses for their breathlessness versus 6 (26%) patients in usual care.
  • Between group differences were greater than MCIDs for several of the PROMs (Table 1).
➤ Semi-structured interviews were completed with 34/48 patients and 10 clinicians. Key themes were identified (Figure 3).
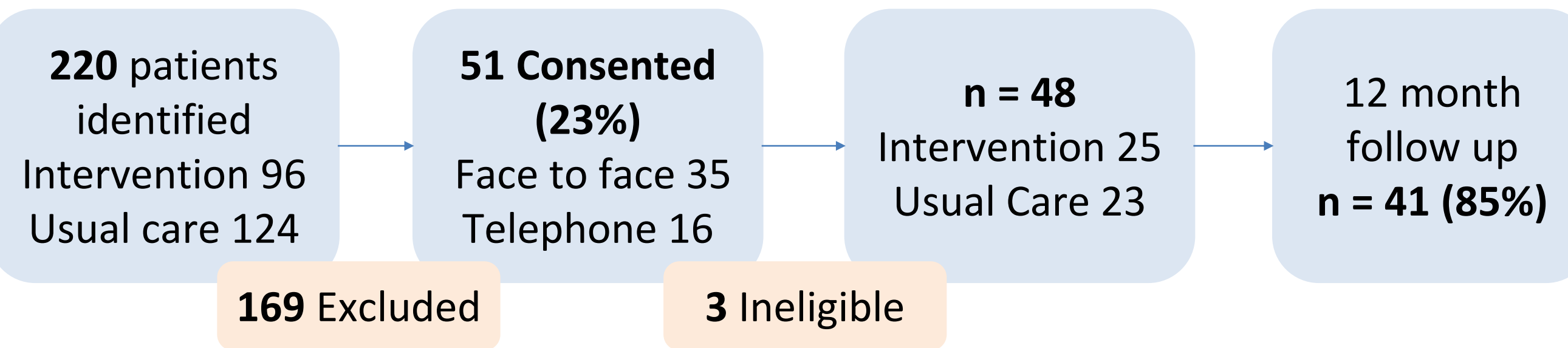
Figure 2. Participant flow diagram

220 patients identified
Intervention 96
Usual care 124

→ 51 Consented (23%)
Face to face 35
Telephone 16

→ n = 48
Intervention 25
Usual Care 23

→ 12 month follow up
n = 41 (85%)

169 Excluded   3 Ineligible

Table 1. Comparison of change in PROM from baseline to 12 months between groups

	MCID	Between group difference at 12 months
MDP		
Immediate perception	- 4.6	-15.4 (3.7)*
Emotional response	- 2.4	-8.2 (3.9)*
Dyspnoea-12	- 2.8	-6.3 (2.7)*
CHQ		
Dyspnoea	+ 0.5	1.0 (0.5)*
HADS		
Anxiety	- 1.7	0.3 (0.1)
Depression	- 1.7	0.5 (1.1)
EQ5D-5L		
Utility Index	+ 0.051	0.11 (0.07)*
VAS	+ 6.9	-6 (5)

*between group change is greater than minimal clinically important difference (MCID) at 12 months

Data is presented as Mean (SE) for between group difference. VAS = Visual Analogue Scale.

Figure 3. Key themes identified from Patient and Clinician Interviews

- Recognising and validating symptoms
- Clinical decision-making
- Difficult conversations
- Differing priorities
- Clinician communication affecting patient experience

"went to see my GP about another problem...and then you say a throwaway thing, you know...and I have problems with breathlessness."

"In general practice we try and be fairly focused... try and do the investigations likely to show you what's going on"

"...you believe that it's due to deconditioning, weight gain, there's not a specific pathology and patients are challenging you on that"

"Once you get the actual formal diagnosis of COPD and then we maybe get into the disease management side of things"

"I feel my next breath is going to be my last one. And his comments were 'Well that's a bit extreme'"

Conclusion

➤ Findings suggest a future fully powered cRCT trial is feasible.
➤ Participants allocated to the structured diagnostic pathway underwent more investigations and a higher proportion had a coded diagnosis at 12 months compared with usual care.
➤ PROMs indicate patient level benefit signalling potential for a more pro-active diagnostic approach.
➤ Themes from the interviews identified disparity between patients and clinicians over symptom validation, communication and breathlessness management.
➤ An adequately powered clinical trial is needed to investigate further.

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