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PRIMARY-HF: Heart Failure Screening in Primary Care using Point-of-Care

PRIMARY-HF: Diagnóstico de Insuficiência Cardíaca em Cuidados de Saúde Primários com *Point-of-Care*

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ABSTRACT

Introduction: Heart failure is a major health challenge with high morbidity and socioeconomic burden, especially when diagnosis is delayed. In primary care, HF detection can be challenging due to symptoms overlapping with other conditions, limited access to diagnostic tools, and resource constraints. This study explores the use of natriuretic peptides (NT-proBNP) and point-of-care ultrasound (POCUS) with artificial intelligence integration as tools to improve HF screening and management in primary care. This study aims to determine whether NT-proBNP testing alone or combined with cardiac POCUS improves heart failure diagnosis and management in primary care settings, and to evaluate the cost-effectiveness of this approach.

Methods: This randomized controlled trial will involve patients aged 50 or older with suspected HF or cardiovascular risk factors, recruited across four primary care centers. Participants will be randomly assigned to one of four groups: standard of care (SoC), SoC with NT-proBNP, SoC with NT-proBNP and POCUS, and SoC with POCUS. Primary outcomes include new HF diagnosis, initiation of guideline-directed medical therapy, and improvement in health-related quality of life. Secondary outcomes include cost-effectiveness and the quality assessment of POCUS performed by trained primary care physicians. The integration of NT-proBNP and POCUS in primary care may enhance early heart failure diagnosis, optimize therapy, improve patient quality of life, and reduce healthcare costs associated with heart failure misdiagnosis and delayed treatment. This study could support the broader adoption of accessible diagnostic tools to improve heart failure management in primary care.

Keywords: Biomarkers; Echocardiography; Heart Failure/diagnosis; Heart Failure/diagnostic imaging; Natriuretic Peptide; Point-of-Care Systems; Primary Health Care

RESUMO

Introdução: A insuficiência cardíaca apresenta uma elevada morbilidade e um importante impacto socioeconómico, especialmente quando o diagnóstico é tardio. Nos cuidados de saúde primários (CSP), a deteção de insuficiência cardíaca é mais desafiante devido à sobreposição de sintomas com outras condições clínicas, ao acesso limitado a ferramentas de diagnóstico e às restrições de recursos. Este estudo explora o uso de péptidos natriuréticos (NT-proBNP) e ecografia *point-of-care* (POCUS) com integração de inteligência artificial (IA) como ferramentas para melhorar a seleção e gestão da insuficiência cardíaca nos CSP. O objetivo deste estudo é avaliar se a realização de testes de NT-proBNP combinados ou não com ecografia cardíaca POCUS melhoram o diagnóstico e a gestão da insuficiência cardíaca nos CSP, bem como avaliar a relação custo-eficácia desta abordagem.

Métodos: Este ensaio clínico controlado e randomizado incluirá pacientes com idade igual ou superior a 50 anos com suspeita de insuficiência cardíaca ou fatores de risco cardiovascular, recrutados em quatro centros de CSP. Os participantes serão aleatoriamente alocados a um de quatro grupos: *standard of care* (SoC), SoC com NT-proBNP, SoC com NT-proBNP e POCUS e SoC com POCUS. Os *outcomes* primários incluem novos diagnósticos de insuficiência cardíaca, início de terapêutica médica orientada por *guidelines* e melhoria na qualidade de vida relacionada com a saúde. Os *outcomes* secundários incluem a relação custo-eficácia e a avaliação da qualidade do POCUS realizado por médicos de CSP treinados. A integração do NT-proBNP e do POCUS em CSP poderá melhorar o diagnóstico precoce de insuficiência cardíaca, otimizar a terapêutica, melhorar a qualidade de vida dos pacientes e reduzir os custos de saúde associados ao diagnóstico incorreto e ao tratamento tardio da insuficiência cardíaca. Este estudo poderá vir a apoiar a adoção mais ampla de ferramentas de diagnóstico acessíveis para melhorar a gestão da insuficiência cardíaca nos CSP.

Palavras-chave: Biomarcadores; Cuidados Primários de Saúde; Ecocardiografia; Insuficiência Cardíaca/diagnóstico; Insuficiência Cardíaca/diagnóstico por imagem; Peptídeo Natriurético; Sistemas Automatizados de Assistência Junto ao Leito

INTRODUCTION

Background and rationale

Heart failure (HF) is a condition that poses a substantial clinical and socioeconomic burden. In Portugal, it is estimated that 16% of the population aged 50 or older suffers from heart failure, but only 10% of them are aware of their condition. These are preliminary findings from the Portuguese Heart Failure Prevalence Observational Study (PORTHOS), the largest and most recent epidemiological study on heart

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failure in Portugal.[1] In primary care, early identification of HF is challenging due to the overlap of symptoms with other conditions such as obesity, pulmonary disease, and general fatigue, which can obscure the clinical presentation. While recent policy changes have improved access to natriuretic peptide testing (NT-proBNP) in primary care, the use of advanced diagnostic tools, such as point-of-care ultrasound (POCUS), remains limited. Although echocardiography is accessible through conventional referral pathways, POCUS, as an immediate and practical tool for enhancing diagnostic precision in primary care, is not routinely available.[2,3]

Point-of-care ultrasound is already considered an extension of the physical examination presently carried out by family physicians in several countries, such as Norway, Canada, Germany, and Spain, where there is evidence of the utility of POCUS performed by family physicians for detecting cardiac abnormalities, such as left ventricular hypertrophy and structural anomalies.[4-6] These tools provide complementary information: NT-proBNP aids in the biochemical identification of heart failure, while POCUS offers real-time visualization of cardiac function and structure, helping in the confirmation or exclusion of heart failure, as well as in the identification of cardiac abnormalities that may require a prompt referral (e.g., severe valvulopathy, marked hypertrophy, segmental alterations, indirect signs of pulmonary hypertension or reduced left ventricular ejection fraction).

The primary objective of this study is to assess whether the integration of NT-proBNP testing and POCUS in primary care improves the diagnosis of HF, while improving HF guideline-directed medical treatment (GDMT), and patient's health status.

Trial design

This is a randomized controlled interventional trial, with four arms and an open-label design. The allocation ratio is 1:1:1:1, comparing different combinations of NT-proBNP testing and POCUS in heart failure diagnosis.

METHODS

Study setting

The study will be conducted across several primary care units in Portugal.

Training program for investigators in echocardiography

The training program will consist of theoretical and practical components, along with assessments to ensure proficiency:

1. Theoretical training:
   - Pre-test: Investigators will take a brief pre-test to assess their baseline knowledge of cardiac anatomy and echocardiographic principles.
   - Self-study: Investigators will complete four hours of self-study at home, focusing on cardiac anatomy, fundamental ultrasound concepts, and basic echocardiographic windows.
   - In-person learning: Following self-study, investigators will participate in four hours of in-person theoretical training led by two experienced family medicine physicians to reinforce the acquired knowledge and address any knowledge gaps identified in the pre-test.
2. Practical training:
   - Investigators will observe five POCUS echocardiographic tests performed by two trained family physicians (each with four months of practical training at a certified echocardiography laboratory, where they observed 200 echocardiograms and independently performed 50 complete echocardiograms, followed by the execution of over 400 cardiac POCUS during clinical practice).
   - Supervised tests: Investigators will perform five tests under supervision, with feedback sessions after each to identify and address areas for improvement.
   - Independent tests: Investigators will then conduct 10 tests independently. The images obtained will be reviewed by an expert cardiologist (European Association of Cardiovascular Imaging - EACVI accredited) to assess quality and accuracy.
   - Mentorship: Investigators will be assigned mentors (the family medicine physicians) who will provide continuous support during their independent phase.
3. Final assessment:
   - A theoretical examination will be conducted to assess knowledge retention and understanding.
   - Upon validation of both theoretical and practical skills, investigators will be certified as proficient in cardiac POCUS.

Eligibility criteria

- Inclusion criteria**:** Patients aged 50 years or older with suspected heart failure (based on signs and symptoms) or known cardiovascular risk factors (at least two of: diabetes *mellitus*, arterial hypertension, eGFR CKD-EPI < 60 mL/min, albuminuria, coronary artery disease or history of myocardial infarction or coronary revascularization, stroke or transient ischemic attack, atrial fibrillation or flutter, left ventricular hypertrophy (LVH) or Q waves on ECG, obesity with a BMI of 30 or greater).[7]
- Exclusion criteria: Patients with known heart failure

already under hospital management, terminal disease, severe comorbidities with life expectancy of less than one year, or inability to provide informed consent.

Interventions

The study involves four groups (Fig. 1):

- Group 1: Standard care (no NT-proBNP, no POCUS).
- Group 2: Standard care and NT-proBNP.
- Group 3: Standard care and NT-proBNP and POCUS.
- Group 4: Standard care and POCUS.

Initial assessment

Supervising physicians will carry out the initial assessment. Patients with suspected HF will be re-evaluated by investigators.

NT-proBNP Testing:

- If NT-proBNP < 100 pg/mL: HF is excluded.
- If NT-proBNP ≥ 100 pg/mL:
  - Physicians without POCUS: Request a conventional echocardiogram.
  - Physicians with POCUS: Perform POCUS and follow these criteria:
    - LVEF* < 50% or LVEF ≥ 50% with structural abnormalities (e.g., LVH** or LA enlargement***): Confirms HF.
    - Absence of these criteria: HF is excluded.
    - If uncertain, an echocardiogram is requested.

* LVEF obtained with the ultrasound AI generation;
** LV mass index ≥ 95 g/m^2 (female), ≥ 115 g/m^2 (male), or relative wall thickness > 0.42;
*** LA volume index > 34 mL/m^2 (sinus rhythm) or > 40 mL/m^2 (atrial fibrillation).

Monitoring adherence

Enrolled patients will be contacted at baseline, three, six, nine and 12 months (study close-out) for the application of the Kansas City Cardiomyopathy Questionnaire (KCCQ12)[8,9] and the *Medidas de Adesão ao Tratamento* (MAT) scale[10] to monitor their health status, quality of life, and treatment adherence. Physicians involved in the study will ensure adherence to the diagnostic and follow-up protocols. If a patient begins hospital follow-up for heart failure or requests to leave the study of their own free will, they will be excluded from the study.

Outcomes

- Primary outcomes:
  - New heart failure diagnosis.
  - Initiation of GDMT.
  - Improvement in health-related quality of life (measured by KCCQ12).
- Secondary outcomes:
  - Cost-effectiveness of NT-proBNP and POCUS in primary care.
  - Assessment of the quality of cardiac POCUS performed by trained family physicians.

Participant timeline

Explanation (Table 1):

- Enrolment phase (-t1):
  - Eligibility screening and informed consent will be conducted before the allocation.
- Allocation (timepoint 0):
  - Participants are randomly assigned to one of the four groups.
- Post-allocation assessments (t1 - t4):
  - At each timepoint (every three months), the KCCQ12 and MAT scale will be applied to monitor quality of life and adherence to treatment.
  - Outcome variables related to heart failure diagnosis, hospitalization, and other clinical outcomes will also be assessed at these intervals.

Sample size

The primary pragmatic comparison will be between Group 4 (Standard of Care + POCUS alone) and Group 1 (Standard of Care). Based on the following assumptions:

- An expected new HF diagnosis rate of 30% in Group 1 (Standard Care).
- An expected increase to 60% in new HF diagnosis with the addition of POCUS in Group 4.

To detect a doubling in the HF diagnosis rate with 80% power and an alpha level of 0.05, a minimum of 40 patients per group (160 total) is required. Randomization will be conducted in a 1:1:1:1 ratio, ensuring an even distribution of approximately 40 patients per group. The follow-up period will be 12 months, allowing clinicians sufficient time to optimize HF therapies or refer patients for hospital appointments if needed.

Comparisons between Group 4 and Groups 2 (Standard Care + NT-proBNP) and 3 (Standard Care + NT-proBNP + POCUS) will be exploratory, with the aim of determining non-inferiority. Since the proportions of GDMT initiation, specialty referral, and KCCQ-12 changes are dependent on new HF diagnoses, the power calculation is based exclusively on new HF diagnosis rates.

Recruitment

Recruitment will be carried out across multiple primary care units in Portugal. The strategy includes:

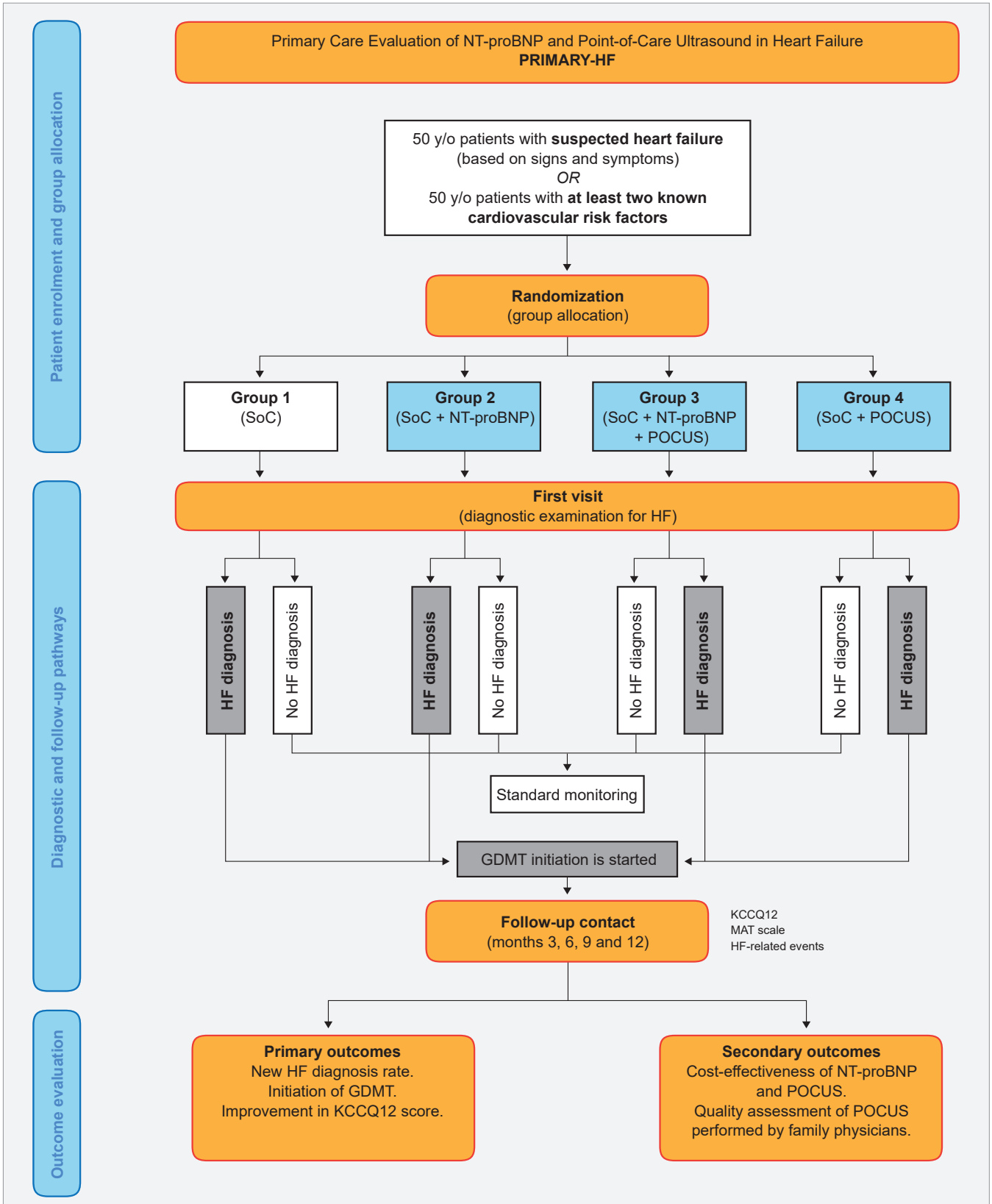

Figure 1 – Flowchart that illustrates the structure and process of the PRIMARY-HF study
GDMT: guideline-directed medical therapy; HF: heart failure; KCCQ12: Kansas City Cardiomyopathy Questionnaire 12; MAT: Medication Adherence Scale; POCUS: point-of-care ultrasound; SoC: standard of care.

1. Target population and enrolment:
   - Patients aged 50 or older with clinical suspicion of heart failure or known cardiovascular risk factors will be identified and recruited during routine visits by family physicians working at the participating primary care units.
2. Awareness campaigns:
   - Educational sessions will be organized at participating clinics to inform potential participants about the study's benefits and the role of NT-proBNP and POCUS in diagnosing heart failure.
3. Sustained recruitment efforts:
   - Recruitment is planned for a period of three months to ensure that the target sample size of 160 participants is achieved.
4. Retention measures:
   - Participants will be contacted regularly every three months for follow-up assessments (KCCQ12 and MAT scale). Flexible scheduling and reminder systems will be implemented to maximize retention and minimize dropout rates.

Methods: assignment of interventions

Sequence generation: The randomization sequence will be generated using a computer-based random number generator. The allocation ratio will be set to 1:1:1:1, ensuring an equal distribution of approximately 40 participants per group.

Allocation concealment mechanism: To maintain allocation concealment, sequentially numbered opaque sealed envelopes will be used. Each envelope will contain the assigned intervention group and will be opened only after the participant has provided informed consent and met all eligibility criteria.

Implementation: The randomization sequence will be generated centrally by the coordinating team at the Faculty of Medicine, University of Porto. Family physicians at each participating primary care site will be responsible for enrolling participants. Once eligibility is confirmed and informed consent is obtained, the assigned intervention group will be revealed by the site physician using the sealed envelope corresponding to the patient's sequence number.

Blinding: This is an open-label study, and neither the participants nor the physicians will be blinded to the intervention groups. Since the interventions (use of NT-proBNP testing and/or POCUS) are not amenable to blinding, all parties involved will be aware of the group assignments. No unblinding procedures are required.

Methods: data collection, management, and analysis

Data collection methods: data will be collected at baseline and during each follow-up visit (every three months for up to 12 months) using standardized electronic forms. The following measures will be taken to ensure data quality and consistency across all sites:

Table 1 – Timeline for the PRIMARY-HF study, detailing the enrollment, allocation, and follow-up assessments over a 12-month period. It includes eligibility screening, informed consent, intervention allocation, and evaluations such as KCCQ12 and MAT scale to monitor patient quality of life and adherence.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	**-t1**	**t0**	**t1** (3 months)	**t2** (6 months)	**t3** (9 months)	**t4** (12 months)
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS						
Group 1 (SoC)		X				
Group 2 (SoC + NT-proBNP)		X				
Group 3 (SoC + NT-proBNP + POCUS)		X				
Group 4 (SoC + POCUS)		X				
ASSESSMENTS						
Baseline variables		X				
KCCQ12 and MAT Scale			X	X	X	X
Outcome variables			X	X	X	X

GDMT: guideline-directed medical therapy; HF: heart failure; KCCQ12: Kansas City Cardiomyopathy Questionnaire 12; MAT: Medication Adherence Scale; POCUS: point-of-care ultrasound; SoC: standard of care

- Baseline assessment: Includes demographic and clinical variables such as age, medical history, NT-proBNP levels, and baseline KCCQ12 and MAT scores.
- Follow-up assessments: Conducted every three months using the KCCQ12 to monitor health-related quality of life and the MAT scale to evaluate treatment adherence.
- Additional variables: Any new heart failure diagnoses, changes in therapy, or hospitalizations will be recorded during follow-up.

To maintain data quality, physicians and study staff will receive training on data collection procedures. Regular monitoring visits by the coordinating team will verify the accuracy and completeness of collected data. Participants who discontinue the study will have their data analyzed up to the last follow-up point.

Economic impact assessment

Metrics

- Direct costs: Assess the reduction in the number of traditional echocardiograms performed.
- Indirect costs:
  - Patient time savings: Calculate the average time saved per patient by avoiding traditional echocardiograms and extrapolate this to the total number of patients in the study.
  - Opportunity costs: Assess opportunity costs related to lost work or daily activities due to additional tests and consultations, calculating the average cost per patient.

Data management: Data will be securely entered into a password-protected electronic database designed for clinical research. Key data management procedures include:

- Double data entry: To minimize errors, all data entries will undergo a double-entry process.
- Range checks and validations: Automatic range checks and data validation algorithms will ensure data consistency and accuracy.
- Data anonymization: all participant data will be anonymized before analysis, with unique identifiers stored separately in an encrypted file accessible only to authorized personnel.

Data will be stored on a secure server, with regular backups and restricted access. The study will comply with GDPR and local data protection regulations.

Statistical methods

Primary and secondary outcomes will be analyzed using the win ratio method as follows:

- Win ratio command: The hierarchical primary outcome will be tested using the 'winratio' package in Stata® with the command winratio id group, outcomes (newhf c > hftrt c > qol c >).
  - id: Unique patient identifier.
  - group: Dummy variable where '0' represents Group 1 (Standard Care) and '1' represents Group 4 (Standard Care + POCUS).
  - outcomes:
    - newhf: Categorical variable for new heart failure diagnosis, testing the hypothesis of a higher proportion of new diagnoses in Group 4 versus Group 1 at 12 weeks.
    - hftrt: Categorical variable assessing GDMT initiation or specialty referral at 12 weeks.
    - qol: Continuous variable representing the change in health status using KCCQ-12 scores from baseline to 12 weeks.

Subgroup analyses and additional tests

- Exploratory analyses will compare Groups 2 and 3 to Group 4 for non-inferiority, focusing on the effects of NT-proBNP and POCUS combined.
- Subgroup analyses will explore differential effects based on age, sex, and comorbidities.

Handling of missing data

- Missing data will be addressed using multiple imputation techniques to minimize bias. Sensitivity analyses will be conducted to compare outcomes with and without imputed data, ensuring robustness.

Methods: monitoring

Data monitoring: A formal data monitoring committee (DMC) is not required due to the low-risk nature of the study. The coordinating team at the Faculty of Medicine, University of Porto, in collaboration with the ethics committees, will oversee the study and conduct internal reviews.

Harms: All adverse events related to NT-proBNP testing and POCUS will be recorded during follow-up visits. Physicians will report any unintended effects to the coordinating team within 24 hours. The coordinating team will evaluate these events and decide on further action in consultation with ethics committees if necessary.

Auditing: No external audits are planned. However, the coordinating team will perform periodic internal audits to ensure compliance with the protocol and verify data accuracy.

Ethics and dissemination

Research ethics approval: The study protocol will be reviewed by the ethics committees of the health institutions where the intervention and data collection will take place and the ethics committee of the Faculty of Medicine, University of Porto. All procedures will comply with the Declaration

of Helsinki.

Protocol amendments: Any amendments to the study protocol will be submitted for approval to the ethics committees and communicated to investigators, participants, and registered trial platforms.

Consent or assent: Informed consent will be obtained from all participants before any study procedures begin.

Confidentiality: Participant data will be anonymized and stored in a secure, password-protected database.

Access to data: Access to the final dataset will be limited to the principal investigator and authorized personnel

Ancillary and post-trial care: There are no specific provisions for ancillary or post-trial care.

Appendices

Informed consent materials: A detailed informed consent form will be developed and provided to participants, outlining the study's purpose, procedures, risks, and benefits. The form will be available in Portuguese and reviewed by ethics committees for approval.

Biological specimens: If the study involves the collection of biological specimens (e.g., blood for NT-proBNP testing), procedures for collection, storage, and analysis will be established.

DISCUSSION

The aim of this clinical trial is to identify the most effective strategy for diagnosing HF and the most efficient approach to managing this condition. Recently published data from the PORTHOS study[1] found that 90% of patients with HF were unaware they had the disease, highlighting a significant gap in early diagnosis in Portugal.

The introduction of NT-proBNP and POCUS as diagnostic tools in primary care offers a practical and accessible solution, enabling more accurate screening and the early initiation of treatments. This study will not only test the clinical efficacy of these interventions but also their economic feasibility.

Additionally, the development of POCUS skills among family physicians represents an investment in continuous training, supporting faster diagnosis not only of HF but also of other conditions in the future.

In summary, this clinical trial has the potential to redefine the approach to HF diagnosis and management in Portugal. The results may serve as a foundation for adopting a more integrated, cost-effective, and patient-centered approach, which could be replicated in other primary healthcare settings.

TRIAL REGISTRATION

Unique Protocol Identification Number: PRIMARY-HF2024-NTBNP01. Trial Registration: To be submitted at ClinicalTrials.gov. Version 1.0 dated October 15, 2024.

AUTHOR CONTRIBUTIONS

JS, JPN, JPF, NC: Study conception and design, critical review of the manuscript.

MIMM, MC, TV, AG: Critical review of the manuscript.

All authors approved the final version to be published.

COMPETING INTERESTS

JS received financial payments from Roche for advising.

TV received support for attending meetings and/or travel from the European Union of General Practitioners and Family Physicians (UEMO), the Portuguese Medical Association, the Bulgarian Association of Family Medicine, the BMJ Publishing Group, and DIA Europe; has a an unpaid position as President of the European Union of General Practitioners and Family Physicians (UEMO); is the Editor-in-Chief of Acta Médica Portuguesa, and receives a salary from the Portuguese Medical Association; receives honoraries from the BMJ Publishing Group as Associate Editor in the research team.

All other authors have declared that no competing interests exist.

FUNDING SOURCES

Roche provided NT-proBNP test kits. There was no direct financial support.

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