

# OPTIMISATION OF HEART FAILURE MANAGEMENT IN NURSING HOMES USING POINT-OF-CARE ULTRASONOGRAPHY: HARMONIOUS TRIAL RATIONALE AND DESIGN

## UPORABA OBPOSTELJNE ULTRASONOGRAFIJE ZA IZBOLJŠANJE VODENJA SRČNEGA POPUŠČANJA V DOMOVIH STAREJŠIH OBČANOV: METODOLOGIJA ŠTUDIJE HARMONIOUS

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### ABSTRACT

#### Keywords:

nursing homes, heart failure, point-of-care ultrasonography, volume assessment

**Introduction:** Heart failure is common in the nursing home population and presents many diagnostic and therapeutic challenges. Point-of-care ultrasonography is a bedside method that can be used to assess volume status more reliably than clinical examination. This trial was conceived to test whether point-of-care ultrasonography-guided management improves heart failure outcomes among nursing home residents.

**Methods:** Nursing home residents with heart failure will be enrolled in a multi-centre, prospective, randomised controlled trial. Residents will first be screened for heart failure. Patients with heart failure will be randomised in 1:1 fashion into two groups. Nursing home physicians will adjust diuretic therapy according to volume status for six months. Point-of-care ultrasonography will be used in the test group and clinical examination in the control group. The primary endpoint will be heart failure deterioration, defined as a composite of any of the following four events: the need for an intravenous diuretic application, the need for an emergency service intervention, the need for unplanned hospitalisation for non-injury causes, or death from whatever cause.

**Expected results:** The expected prevalence of heart failure among nursing home residents is above 10%. Point-of-care ultrasonography-guided heart failure management will reduce the number of deteriorations of heart failure in the nursing home population.

**Conclusion:** This study will explore the usefulness of point-of-care ultrasonography for heart failure management in the nursing home population.

### IZVLEČEK

#### Ključne besede:

domovi starejših občanov, srčno popuščanje, obposteljna ultrasonografija, ocena volumnske obremenitve

**Uvod:** Zdravljenje srčnega popuščanja v domovih starejših občanov ima številne diagnostične in terapevtske izzive. Obposteljna ultrasonografija je nova metoda, ki omogoča natančnejšo oceno volumnske obremenitve kot klinični pregled. Namen te raziskave je preizkusiti, ali lahko z uporabo obposteljne ultrasonografije izboljšamo izide stanovalcev domov starejših občanov s srčnim popuščanjem.

**Metode:** Izvedli bomo multicentrični, prospektivni kontrolirani preizkus, ki bo vključil stanovalce domov starejših občanov s srčnim popuščanjem. Sprva bomo presejali stanovalce domov starejših občanov glede srčnega popuščanja. Paciente s srčnim popuščanjem bomo randomizirali 1 : 1 v dve skupini. Zdravniki v domovih starejših občanov bodo 6 mesecev prilagajali diuretiko terapijo glede na volumnsko obremenitev - v testni skupini bodo volumnsko obremenitev ocenjevali z obposteljnimi ultrazvokom, v kontrolni skupini le klinično. Primarni opazovani izid bo poslabšanje srčnega popuščanja, določeno kot pojav kateregakoli od naštetih dogodkov: potrebe po intravenskem antibiotiku ali potrebe po aktivaciji dežurne službe ali potrebe po neplanirani nepoškodbeni hospitalizaciji ali smrti zaradi kateregakoli razloga.

**Pričakovani rezultati:** Pričakovana prevalenca srčnega popuščanja med stanovalci domov starejših občanov je več kot 10-odstotna. Vodenje stanovalcev s srčnim popuščanjem z obposteljno ultrasonografijo bo zmanjšalo število poslabšanj srčnega popuščanja.

**Zaključek:** Ta raziskava bo raziskala uporabnost obposteljne ultrasonografije pri vodenju bolnikov s srčnim popuščanjem v domovih starejših občanov.

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## 1 INTRODUCTION

The nursing home population is specific and challenging from several healthcare perspectives. Most nursing home residents are elderly and have more than one chronic medical condition. Heart failure (HF) is one of the most prevalent chronic conditions. When symptomatic, it affects the health-related quality of life of elderly people (1, 2). Prevalence in those aged 75-84 and >85 years is 9.7 and 17.4% respectively (3, 4) and the prevalence in nursing homes ranges from 15% to 45% (5). HF is associated with a high rate of hospitalisations that are related to increased mortality (5-7).

To cope with the burden of clinical events, definite and timely diagnosis of HF is the key, but several studies have shown that HF is undiagnosed in up to 90% or misdiagnosed in up to 76% of nursing home residents (8, 9). The 2016 European Cardiology Society guidelines provide universal recommendations for the diagnosis and treatment of HF for all age groups (10). However, owing to the limited accessibility of diagnostic and therapeutic procedures, the needs of the nursing home population for secondary healthcare procedures often remain unmet (11, 12). The guidelines for both HF diagnosis and management are frequently not followed in the nursing home population, leading to sub-optimal or even inappropriate HF treatment, frequent instances of deterioration and poor quality of life (13). Both the diagnostics and management of heart failure in the nursing home population therefore remain important challenges for primary care physicians.

Over the last decade, point-of-care ultrasonography (POCUS) has developed into an indispensable tool for bedside patient management, enabling the physician to acquire visual information easily, safely and quickly (14). In the HF management guidelines, POCUS is recommended to assess volume overload, i.e. assessing lung congestion, pleural effusion and inferior vena cava diameter (10, 15). To date, POCUS has been mostly studied for dichotomous decision-making in acute HF (16, 17), while the usefulness of POCUS in chronic HF management has not been widely investigated (18). Recent studies show that an estimate of sub-clinical lung congestion using POCUS is an important predictive factor for HF outcome in ambulatory patients (19). This enables the primary care physician to promptly adjust diuretic therapy in order to prevent a HF deterioration.

This trial was conceived to test whether point-of-care ultrasonography-guided management improved HF outcomes among nursing home residents.

The following issues were specifically addressed:

1. What is the prevalence of HF in nursing homes?
2. Does POCUS-guided HF management reduce the number of HF deteriorations in the nursing home population?
3. Should POCUS be integrated into the algorithm of HF management for the nursing home population?

## 2 METHODS

### 2.1 Study Design

A multi-centre, prospective, randomised controlled trial will be conducted.

### 2.2 Setting

Selected nursing home facilities provide long-term care for over 1,000 residents in several locations. Nursing home care is provided by a multidisciplinary team. Nursing home physicians are family medicine specialists who are responsible for all medical care, including the initiation of different diagnostic and therapeutic interventions, and palliative care.

### 2.3 Study Population

The population will consist of nursing home residents. The demographic characteristics of this population are expected to reflect the general population in this age group with an average age of over 80 years and predominantly female.

### 2.4 Inclusion and Exclusion Criteria

Inclusion criteria will be: a) nursing home residents and b) consent to participate in the study by the participant or by their legal representative. Exclusion criteria will be a) life expectancy of fewer than six months for a reason other than heart failure, b) residents on short-term or day care and c) residents unable to complete HF diagnostics for any reason.

This population will be screened for HF using 2016 ESC guidelines for HF diagnosis, regardless of any pre-existing HF diagnosis (10). All nursing home residents with heart failure will be included in the intervention part of the study.

### 2.5 Selection of Participants

The residents or their legal representatives will receive a letter describing the purpose and content of the study, an informed consent form, and a data administration consent form consistent with the EU General Data Protection Regulation (2016/679). If needed, residents will be able to obtain a further explanation of the study from the research coordinator at the nursing home.

### 2.6 Training of Nursing Home Physicians

Nursing home physicians are presumed to be skilled in the management of heart failure. However, they will be encouraged to review the recent European guidelines on heart failure management (10) and will be able to consult a cardiologist at any time.

Family medicine specialists are presumed to have no prior knowledge of bedside ultrasonography. They will

undergo a four-hour supervised training session on the handling of the POCUS device and on the use of POCUS for volume assessment. The physicians will be trained in the assessment of B-lines in eight standard positions in a supine patient (Figure 2) and in the visualisation of the inferior vena cava, assessing its size and collapsibility (Table 2). During training, they will perform at least five supervised POCUS volume assessments. Later on, they will independently perform ten POCUS volume assessments, with the images being recorded. The recorded images will be evaluated and skill will be further developed under supervision if needed. An experienced POCUS provider will confirm the skill level achieved three weeks after the initial training.

## 2.7 Study Protocol

The study protocol will consist of screening and intervention parts. It will follow the scheme presented in Figure 1.

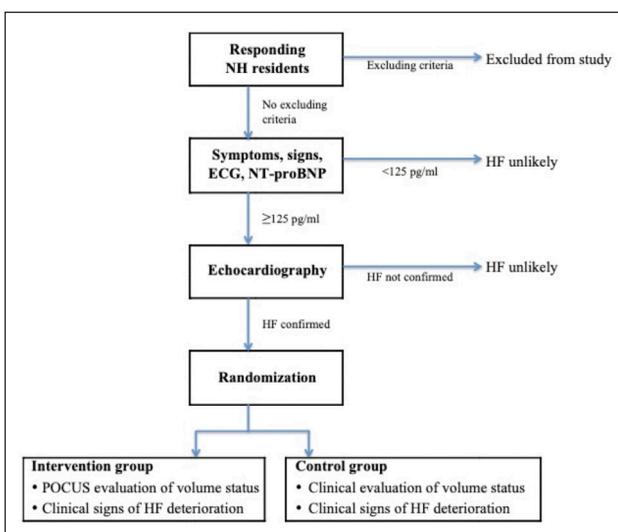


Figure 1. Study protocol scheme.

### 2.7.1 Screening of HF

Screening for HF will follow the 2016 European Cardiology Society diagnostic algorithm for the diagnosis of HF of non-acute onset (10). All screening stages will take place in nursing home facilities.

The diagnostic procedure to determine HF will include: 1) the assessment of HF probability by assessing clinical history, clinical signs and ECG, 2) the NT-proBNP measurement and 3) the echocardiography with clinical judgement.

### 2.7.2 Assessment of HF

With the help of two junior researchers, the nursing home physicians will review residents' history and perform a clinical examination to identify clinical signs of heart failure. They will have full access to residents' medical records and will be able to assess multimorbidity. Trained nursing home staff will record ECG and collect blood samples for measurement of the NT-proBNP marker. NT-proBNP will be measured using a Roche Cobas h 232 point-of-care system on site. The ECG will be interpreted by a nursing home physician. A qualified cardiologist will perform the echocardiography exam using a GE Vivid 7 ultrasound system. While performing echocardiography, the cardiologist will be blinded for NT-proBNP value and will perform echocardiography on an additional 10% of NT-proBNP negative patients as a control measure. A pre-defined ultrasonography protocol will be followed and images and clips recorded.

### 2.7.3 Diagnosis and Initial Treatment of Heart Failure

After performing echocardiography, the cardiologist will have access to all patient data to diagnose or exclude HF. The current classification of HF will be used: heart failure with preserved (HFpEF), mid-range (HFmrEF) and reduced ejection fraction (HFrEF). For the diagnosis of HFmrEF and HFpEF, the following requirements will have to be met: presence of symptoms and/or signs of heart failure, left ventricular ejection fraction (LVEF) of  $\geq 50\%$  or 40-49%, NTproBNP  $\geq 125$  pg/mL, and objective evidence of other cardiac functional and structural alterations underlying heart failure.

At the inclusion point, the cardiologist performing echocardiography will recommend a therapeutic management plan for HF patients. The cardiologist and the nursing home physicians will jointly optimise medication therapy, with due consideration given to current medication guidelines and the individual patient's characteristics. From this point on, the patient will be managed by the nursing home physician.

### 2.7.4 Randomisation

Patients diagnosed with HF will be randomised using block randomisation (block  $n=10$ ) into intervention and control groups. The randomisation list will be performed by an independent statistics adviser. For the randomisation process, patients' identification numbers will be used in place of a name. This is to avoid randomisation bias. The research coordinator will perform randomisation by applying the sealed envelope technique (20).

### 2.7.5 Intervention

Nursing home physicians will manage HF patients for six months by assessing volume status and aiming to prevent any significant HF deterioration. The volume assessment will be performed using POCUS and clinical signs in the intervention group, and only clinically in the control group. Patients in the control group will receive standard care in line with current HF guidelines and good clinical practice by the nursing home physician. The intervention group will receive the same clinical standards plus POCUS for volume evaluation.

The follow-up of both the test and control groups will last for six months. The patients will be evaluated at regular time intervals, as presented in Table 1. Unplanned evaluations will be performed whenever HF deterioration is suspected and one week after diuretic therapy change.

In the intervention group, nursing home physicians will use Samsung SonoAce R3 point-of-care devices. POCUS volume assessment will consist of the visualisation of B-lines on eight standard positions: the mid-clavicular line in the second and fourth intercostal spaces bilaterally, and the mid-axillary line in the second and fourth intercostal spaces bilaterally (Figure 2) (21). Inferior vena cava diameter and collapsibility will also be evaluated, as presented in Table 2.

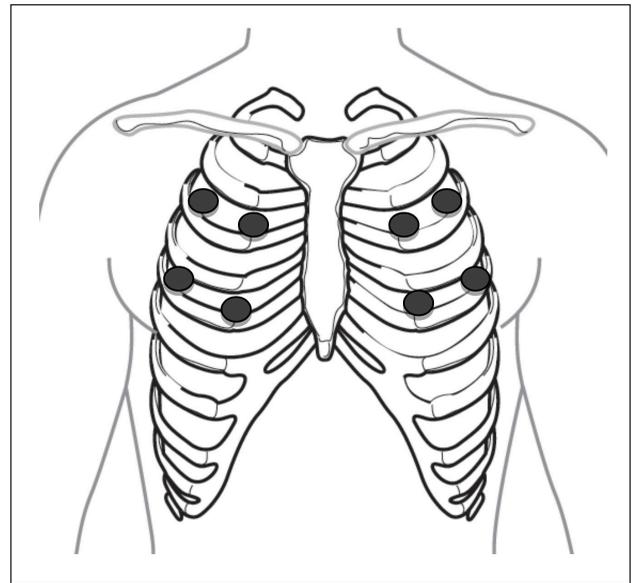


Figure 2. Eight standard positions for visualisation of B-lines in lung POCUS.

The inferior vena cava diameter and collapsibility will be assessed 2 cm below the junction with the right atrium (22, 23). It will be categorised as small, medium or large. The inferior vena cava will be considered collapsible if the inspiratory collapse is more than 50% of its diameter.

Table 1. Follow-up plan.

	Test-retest reliability	At inclusion				
Intervention group	Physical examination	+	+	+	+	-
	POCUS	+	+	+	+	-
	Evaluation of HF deteriorations	+	+	+	+	+
Control group	Physical examination	+	+	+	+	-
	POCUS	+	-	-	-	-
	Evaluation of HF deteriorations	+	+	+	+	+

Table 2. Inferior vena cava diameter and collapsibility evaluation (adapted and modified from Kircher, et al. (22) and Papadimos, et al. (23)).

Category	Estimated inferior vena cava diameter	Collapsibility	Estimated central venous pressure
Small	<1.5 cm	>50%	0-5 mm Hg
Medium	1.5-2.5 cm	>50%	6-10 mm Hg
		<50%	11-15 mm Hg
Large	>2.5 cm	<50%	>16 mm Hg

### 2.7.6 Diuretic Modifications

Nursing home physicians will monitor patients with HF for signs of volume overload. Volume overload will be assumed if any new HF-related symptoms appear (breathlessness, orthopnoea, paroxysmal nocturnal dyspnoea, reduced exercise tolerance, fatigue, tiredness, increased time to recover after exercise) that are consistent with any clinical signs of HF (pulmonary crepitation, ankle swelling, elevated jugular venous pressure, hepatojugular reflux, gallop rhythm, laterally displaced apex, weight change >2 kg/week).

Additionally in the POCUS group, volume overload will be assumed if at least three B-lines are present in at least five out of eight regions of the thorax or if the inferior vena cava is found to be large (>2.5 cm) or medium-sized, but non-collapsible.

Volume depletion will be assumed if B-lines are absent and the inferior vena cava is small and not collapsible, together with clinical signs of volume depletion.

If the nursing home physicians assess volume overload, they will double the daily dose of diuretic and re-evaluate the patient in one week. If they find the patient volume depleted one week after the increase of the dose of diuretic, they will halve the daily dose of diuretic back to the initial dose.

### 2.7.7 Workload Evaluation

The use of POCUS will also be assessed from the perspective of potential additional workload for nursing home physicians. The workload will be monitored with regard to the number of non-administrative contacts, therapy modifications and referrals. Furthermore, technical and other requirements for POCUS in NH will be documented.

## 2.8 Endpoints

### 2.8.1 Primary Endpoint

The primary endpoint will be HF deterioration, defined as a composite of any of the following four events: the need for an intravenous diuretic application, the need for an emergency service intervention, the need for unplanned hospitalisation for non-injury causes, or death from whatever cause.

### 2.8.2 Secondary Endpoints

Secondary endpoints will be:

1. A change in quality of life (self-evaluated)
2. A change in functional state caused by HF using the New York Heart Association (NYHA) score
3. The need for an intravenous diuretic application
4. The need for an emergency service intervention

5. The need for unplanned hospitalisation for non-injury causes
6. The number of days in hospital related to HF deterioration
7. The number of days alive and out of hospital
8. Death from whatever cause.

### 2.8.3 Other Outcomes

The workload of nursing home physicians will be measured by counting the number of all and HF-related a) non-administrative contacts, b) therapy modifications and c) unplanned non-injury referrals.

## 2.9 Statistical Analysis

### 2.9.1 Sample Size Calculation

The calculation of sample size was based on an estimated prevalence of HF in nursing home residents of  $p=0.25$  and on an estimated incidence of heart failure composite events in six months of 50% (6, 17).

In the intervention part of the research, we aim to decrease the number of patients with HF deterioration from 50% to 20% in six months. With a study power of 80% and an estimated statistical error of 5%, at least 90 residents with heart failure need to be included in the randomised controlled trial. With an expected prevalence of heart failure of  $p=0.25$ , at least 360 residents should be recruited for HF screening.

The rate of response/participation in clinical studies in this population is expected to be about 30% (25). It will therefore probably be necessary to approach approx. 1,000 nursing home residents in order to yield 360 residents for HF screening.

### 2.9.2 Data Analysis

The data will be analysed using the SPSS statistical software package. We will show frequencies, averages and the standard deviation of variables, or value ranges and median where applicable.

Differences between groups will be tested using appropriate statistical methods, such as the T-test or analysis of variance (ANOVA) for continuous variables, and the Chi-square test and multivariable logistic regression analyses for discrete variables.

As statistical significance, a  $p$  value of  $<0.05$  will be used.

## 3 MEASUREMENTS

The data required to answer the research questions is presented in Table 3.

**Table 3.** Study data collection list (HF - heart failure; NYHA - New York Heart Association classification; HFrEF - heart failure with reduced ejection fraction; HFmrEF - heart failure with mid-range ejection fraction; HFpEF - heart failure with preserved ejection fraction).

Category	Data variable	Measurement description	Data source
<b>Demographic data</b>	Age	In full years	Medical record
	Gender	Male or female	Medical record
<b>Baseline clinical characteristics</b>	Multimorbidity	Yes if more than 2 chronic diseases	Medical record
	Charlson Comorbidity Index	Using MDCalc software	Medical record
	Previously diagnosed heart failure	Yes if any evidence	Medical record
	Current therapy	Number of all prescribed medicines	Medical record
	Start-point health barometer	Self-evaluated	Interview
	Start-point NYHA	On scale I-IV	Interview and clinical examination
	History of coronary artery disease	Yes if any evidence	Medical record
<b>Clinical history</b>	History of arterial hypertension	Yes if any evidence	Medical record
	Exposition to cardiotoxic drugs/radiation	Yes if any evidence	Medical record
	Use of diuretics	Yes if any evidence	Medical record
	Orthopnoea / paroxysmal nocturnal dyspnoea	Yes if declared or any evidence	Interview or medical record
<b>Signs of heart failure</b>	Rales	Yes if bilateral	Clinical examination
	Bilateral ankle oedema	Yes if bilateral	Clinical examination
	Heart murmur	Yes if heard	Clinical examination
	Jugular venous dilatation	Yes if observed in sitting position	Clinical examination
	Laterally displaced / broadened apical beat	Yes if felt	Clinical examination
<b>Diagnostics of heart failure</b>	ECG	Any abnormality	Study
	NT-proBNP	Positive if $\geq 125$ pg/mL	Study
	Echocardiography	Categorisation in HFrEF, HFmrEF, HFpEF	Study
<b>Outcomes</b>	Events related to HF deterioration	The need for the iv diuretic, the emergency service intervention, hospitalisations for non-injury cause or death	Study
	Days to deterioration of heart failure	For any event related to HF deterioration	Study
	Change in health barometer	Self-evaluated	Study
	Change in NYHA class	On scale I-IV	Study
	Days in hospital due to heart failure	For HF deterioration only	Study
	Days alive and out of hospital	Excluding hospital days for whatever cause	Study
<b>Workload</b>	Days alive	Time to death for whatever cause	Study
	Non-administrative contacts	All and HF related	Study
	Therapy modifications	All and HF related	Study
	Unplanned referrals	All and HF related	Study

### 3.1 Demographic Data and Baseline Clinical Characteristics

Demographic data (age and gender) and baseline clinical characteristics (list of therapy, list of previous medical conditions) will be gathered for all participants by nursing home physicians and researchers. This data will be used to assess multimorbidity, applying the Charlson Comorbidity Index (26) and using free online MDCalc software. Self-evaluation of health using a numerical and visual analogue scale from 0 to 100 will be performed for patients diagnosed with HF, functional state under the New York Heart Association classification (27).

### 3.2 HF Screening and Diagnostics

Symptoms and signs of HF will be obtained for all participants. ECG and NT-proBNP measurement will be recorded. Echocardiography will be performed on all patients with NT-proBNP  $\geq 125$  ng/ml. HF will be classified according to left ventricle ejection fraction (LVEF).

### 3.3 Intervention Outcomes

Events related to HF deterioration will be monitored as a composite event and separately: the need for an IV diuretic, emergency service intervention, hospitalisation for non-injury cause, or death. Days in hospital for HF and days alive and out of hospital will be recorded. The change in the functional state of residents will be determined by the change in the NYHA score and the self-evaluation of health score at the end of the study. Measures related to the workload of nursing home physicians will be monitored: the frequency of non-administrative contacts, therapy modifications and unplanned non-injury referrals.

## 4 DISCUSSION

This study will provide an insight into the use of POCUS for HF management in nursing homes. This is the first study to investigate the use of the point-of-care approach in a nursing home setting and for non-acute disease management.

Nursing home patients with HF must have their need for diuretics continuously evaluated. They are unpredictable in their hydration habits (28) as they often do not drink enough while still ingesting diuretics. It is just as likely that they do not follow individual daily fluid restrictions. They are susceptible to a deterioration in renal function due to diuretic overuse, which can lead to an electrolyte imbalance and acute renal failure. On the other hand, they are sensitive to fluid overload, which can rapidly cause pulmonary congestion and symptomatic HF deterioration. The use of diuretics should therefore be reassessed frequently and monitored closely.

Clinical examination alone is often not sensitive enough to detect subtle changes in the volume status of HF patients. In tandem with a clinical examination, POCUS is a useful and reliable tool for volume status evaluation. It is non-invasive, and is also applicable to patients with limited access to other diagnostic options. The technique of volume assessment using POCUS can be reliably mastered in a short time by different profiles of health workers (18). Using POCUS, volume status is evaluated by assessing inferior vena cava size and by performing lung ultrasonography. The inferior vena cava size reflects fluid intake, and the lung ultrasonography findings change rapidly to diuretic therapy (17, 19). This information enables the prompt dose adjustment of diuretics in response to volume status (18).

This study will be based on actual prevalence of HF. Several studies of HF prevalence in the nursing home population have shown that prevalence is higher than expected in the comparable age group and that HF is often undiagnosed or misdiagnosed (8, 25, 29). There are several factors that make this more likely, but the accessibility and feasibility of diagnostic procedure of HF are the most common (13). To overcome this, and to ensure equity for all participants, the whole diagnostic procedure of HF in this study will be performed on-site in nursing homes.

The follow-up of HF patients enrolled in the study will continue for six months. Based on studies investigating hospital readmissions of HF patients due to deterioration, there is an approximately 50% chance of HF deterioration in this time period and for this age group (6, 17). However, due to the lack of data for the nursing home population, this assumption is based on patients hospitalised for HF. If the incidence of events related to deterioration is lower than assumed, the observed period could be too short or the sample too small. This could be a limitation of the study. Another limitation could be insufficiencies in the POCUS teaching module, as the investigators' POCUS skills will allow them to perform only volume evaluation based on B-lines and VCI size and collapsibility. They will not be able to evaluate any other aspect of HF deterioration or identify any other conditions with similar clinical presentation. In the case of clinically significant deteriorations, nursing home physicians will need to follow standard protocols of care. Other limitations of the study could be a delay in the screening phase of the study, poor performance of POCUS due to increased physician workload, and variability in the diuretic modification in response to volume change.

The originality of this study is in its assessment of the applicability of POCUS for chronic disease follow-up in primary care. The findings might justify a novel approach to HF management in the nursing home population.

## 5 CONCLUSION

The HARMONIOUS trial is designed to test the importance of POCUS performed by nursing home physicians in HF management. The timely and exact assessment of volume status using POCUS might enable optimal diuretic therapy adjustment, resulting in fewer HF-related events. If so, POCUS could be integrated into the algorithm for HF management in the nursing home population.

## CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

## FUNDING

The study will be financed by Department of Family Medicine, Faculty of Medicine, University of Ljubljana, Slovenia, and by the Institute for the Development of Family Medicine, Ljubljana, Slovenia.

## ETHICAL APPROVAL AND REGISTRATION

The authors of this paper hereby declare that the study complies with the Declaration of Helsinki and that it has been approved by the Slovenian National Medical Ethics Committee (KME 41/06/17). The study is registered in the German clinical trial registry (DRKS00012911).

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