

A quasi-experimental study about shared decision-making and motivational interviewing on patients with a recent fracture attending Fracture Liaison Services

[Lieke Maas](#) ,

[Mickaël Hiligsmann](#) ,

[Caroline E Wyers](#) ,

[Sandrine Bours](#) ,

[Trudy van der Weijden](#) ,

[Joop P van den Bergh](#) ,

[Marsha van Oostwaard](#) ,

[Sander M J van Kuijk](#) ,

[Annelies Boonen](#)

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Abstract

Shared decision-making (SDM) aims to improve patients' experiences with care, treatment adherence, and health outcomes. However, the effectiveness of SDM in patients with a recent fracture who require anti-osteoporosis medication (AOM) is unclear. The objective of this study was to assess the effectiveness of a multicomponent adherence intervention (MCAI) including a patient decision aid (PDA) and motivational interviewing at Fracture Liaison Services (FLS) on multiple outcomes compared with usual care (UC). This pre-post superiority study included patients with a recent fracture attending FLS and with AOM treatment indication. The primary outcome was 1-year AOM persistence measured by pharmacy records. Secondary outcomes included treatment initiation, AOM adherence (measured by medication possession ratio [MPR]), decision quality (SDM process; 0–100, best), and decisional conflict (0–100, highest conflict), subsequent fractures, and mortality. Outcomes were tested in MCAI and UC groups at the first FLS visit and 4 and 12 months afterwards. Multiple imputation and uni- and

multivariable analyses were performed. Post hoc analyses assessed the role of health literacy level. In total, 245 patients (MCAI: $n = 136$, UC: $n = 109$) were included. AOM persistence was 80.4% in the MCAI and 76.7% in the UC group ($p = .626$). SDM process scores were significantly better in MCAI (60.4 vs 55.1; $p = .003$). AOM initiation (97.8% vs 97.5%), MPR (90.9% vs 88.3%, $p = .582$), and decisional conflict (21.7 vs 23.0; $p = .314$) did not differ between groups. Results did not change importantly after adjustment. Stratified analyses by health literacy showed a better effect on MPR and SDM in those with adequate health literacy. This study showed no significant effect on AOM persistence; however, it demonstrated a significant positive effect of MCAI on SDM process in FLS attendees. (Netherlands Trial Registry, Trial NL7236 [NTR7435]; version 1.0; 26-11-2020 <https://onderzoekmetmensen.nl/nl/trial/22858>).

[patient decision aid](#), [osteoporosis](#), [shared decision-making](#), [medication persistence](#), [medication adherence](#), [Fracture Liaison Services](#), [anti-osteoporosis medication](#), [fracture](#)

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Lay Summary

When patients participate in the decision-making process (called shared decision-making), we may be able to improve the way they take medication and experience care. We wanted to study how shared decision-making works in people who recently broke a bone and therefore needed anti-osteoporosis medication. We looked at 2 approaches that specialized nurses could use at the clinic. During the first visit, the nurses used a decision aid to discuss different medication options with the patient. During the second visit, nurses used “motivational interviewing” to better understand and support patients with taking their medication in the long term. We compared 109 patients who participated in this study with 126 patients who received normal care without the approaches. We found that the 2 approaches did not change the way people take their medication 1 year after the visits. However, patients who experienced the new approaches felt more involved in all phases of the decision to start and continue medication compared with patients receiving usual care. One year after the visits, people with higher health literacy were more likely to feel like they had been involved in the decision-making process, and more likely to continue to take their medication as prescribed.

Introduction

Fracture Liaison Services (FLS) have been identified as one of the most successful organizational approaches for secondary fracture prevention in patients with a recent fracture aged 50 years and over. The organization of FLS care was driven by the large treatment gap in patients with osteoporosis—defined as the number of patients who need anti-osteoporosis medication (AOM) treatment but do not receive it—estimated at 71% in a large European study.^{1,2} Furthermore, in patients starting AOM, up to 50% discontinue therapy in the first year.³ Despite improvement in secondary fracture prevention due to the increasing number of FLS, data on suboptimal levels of adherence suggest room for improvement in outcomes in FLS.^{4,5}

Adherence to AOM is a complex problem, with substantial clinical and economic consequences.¹ One of the major causes of AOM non-initiation and non-adherence includes the lack of understanding with regard to the consequences of non-treatment.⁶ In addition, it is

important to acknowledge patient preferences and values in initiation and adherence to AOM.⁷ Through shared decision-making (SDM), healthcare professionals (HCPs) and patients discuss benefits and harms of the treatment options as well as patients' values and preferences.⁸ Additionally, the use of patient decision aids (PDAs) can help reduce variation in clinical practice in preference-sensitive options.^{9,10} A dozen PDAs have been developed to support patients in initiating AOM and their evaluation suggested a positive effect on patient engagement in the decision-making process.^{9,11–17} Even fewer randomized controlled trials have been conducted to date, with inconclusive results on medication adherence.^{14,18–20} For example, the randomized pilot study of Smallwood among 50 patients revealed a positive effect of PDA on treatment initiation in the intervention compared with the usual care (UC) group, but no significant effect on AOM adherence and persistence was seen in this small study.²⁰

A recent systematic review revealed that multicomponent adherence interventions (MCAIs) were the most effective interventions when aiming to increase adherence and/or persistence to AOM.¹⁸ Among other intervention components, motivational interviewing in follow-up care has shown a promising impact on AOM persistence and adherence.^{21–25} During motivational interviewing nurses inquire about the patients and their experiences with treatment, adherence to AOM, and any setbacks, and stimulate therapy using specially developed techniques.²²

Despite the need to improve AOM adherence and to respond to patients' values and preferences at FLS, the effects of an MCAI including a PDA complemented by motivational interviewing at the follow-up have not yet been tested among patients with recent fracture attending FLS and requiring AOM. An effective intervention would be of great value as these patients have a high imminent subsequent fracture risk. In view of the known health gap by health literacy limitations, it would be of specific interest whether this intervention has extra effects in patients with limited health literacy.

The Improvement of Osteoporosis Care Organized by Nurses (ICON) study²⁶ was developed to assess the effectiveness of an MCAI combining a PDA²⁷ with motivational interviewing on AOM persistence and patients' experiences with the decision-making process compared with UC in patients with a recent fracture attending FLS. A secondary aim was to report the views and opinions of HCPs and patients on the usage of the MCAI in clinical care through a process evaluation. Last, this study aimed to provide further understanding of the effect of the MCAI on health literacy skills.

Materials and methods

The Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) guideline was used for standardized reporting in nonrandomized evaluations of behavioral and public health interventions.²⁸ The TREND statement is based on the Consolidated Standards of Reporting Trials (CONSORT) statement developed for randomized controlled trials (see [Table S1](#) for a checklist).

Study design and setting

A pre-post study design with a 1-year follow up was chosen to test the superiority of the MCAI compared with UC on AOM persistence and other secondary outcomes. The study was conducted at the FLS²⁶ centers of the Maastricht University Medical Centre+ (MUMC+) and the VieCuri Medical Center Venlo between September 2018 and September 2023. Potential contamination of the UC group by the nurse-administered MCAI was prevented by initiating inclusion of the MCAI group only after the UC group had completed the FLS follow-up visit and

after osteoporosis nurses and the nurse practitioner (hereafter referred to as osteoporosis nurses) were trained in the use of the PDA (applied in the first visit) and conversations (applied in the second visit) according to the motivational interviewing technique. Based on the above-mentioned precautions, sequence generation, blinding, and masking were not required during the trial ([Figure 1](#)).

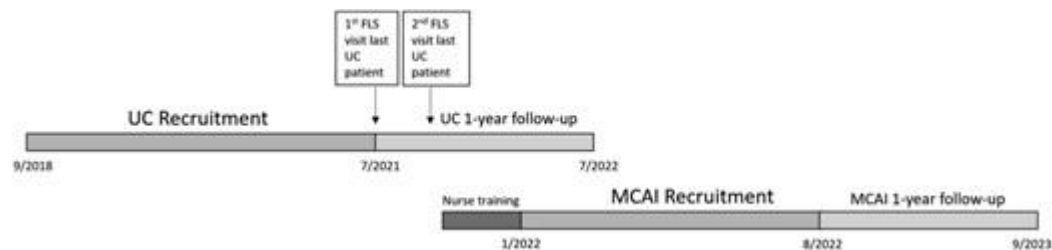


Figure 1

Patient recruitment. Potential contamination of the UC group by the nurse-administered MCAI was prevented by initiating inclusion of the MCAI group and nurse training in the use of PDA and motivational interviewing only after the UC group completed the FLS follow-up visit (referred to in the figure as 2nd FLS visit). Abbreviations: FLS, Fracture Liaison Services; MCAI, multicomponent adherence intervention; PDA, patient decision aid; UC, usual care.

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Study population

Eligible patients included people (1) aged 50 years and older; (2) who attended FLS after a recent fracture (≤ 26 weeks); (3) with a treatment indication according to the Dutch Guideline (defined as a T-score ≤ -2.5 as measured by DXA scans) or according to the model of Genant,²⁹ grade 2 (25%–40%) or 3 ($\geq 40\%$) vertebral fracture; and (4) not having used AOM within 12 months before the FLS visit. Patients were excluded if they (1) had contraindications for oral AOM, (2) had severe comorbidities (eg, current malignancies), (3) were unable to fill in questionnaires due to language barriers, or (4) were treated with intravenous AOM (ie, zoledronic acid).

After the first visit to FLS (2 to 4 months after the fracture), consecutive eligible patients were invited for study participation. Patients willing to participate provided written informed consent for study participation including permission to obtain data from their pharmacy to assess AOM adherence. The Medical Ethics Committee of MUMC+/Maastricht University, the Netherlands, approved this study (registration number 2018-057). The study was registered in the Netherlands Trial Registry, part of the Dutch Cochrane Centre (Trial NL7236 [NTR7435]; version 1.0; 26-11-2020 <https://onderzoekmetmensen.nl/nl/trial/22858>).

Usual care and MCAI

In the UC group, at the first visit, the results of the DXA/vertebral fracture assessment and laboratory tests were discussed by the osteoporosis nurse, including the indication for treatment, which is in line with the Dutch osteoporosis and fracture prevention guideline.³⁰ At the second visit, approximately 4 months after the first FLS visit, the osteoporosis nurse evaluated AOM treatment adherence and possible side effects. Osteoporosis nurses had been informed that patients would be invited to participate in a study on quality of FLS care but were not aware that the main study objective focused on communication and adherence, nor did

they receive any advice on how to explain the pre-visit results or need of treatment with their patients.

Prior to integration of the MCAI in the FLS clinic, the nurses were trained by an expert in the field of healthcare communication and behavioral change. During the first training session, the osteoporosis nurses (4, 2 in each center) were introduced to SDM, PDAs, and motivational interviewing, discussed the PDA that was developed for use in the FLS and were instructed on the use of the PDA and motivational interviewing in practice. During the next few weeks, nurses had to apply the decision tool and motivational interviewing in clinical practice and a second training session was organized to discuss experiences and emerging issues. In practice, the osteoporosis nurse administered the PDA, but the actual decision for AOM initiation was made collaboratively between the osteoporosis nurse/medical specialist and patient.

The PDA was developed through a systematic process, in line with the International Patient Decision Aid Standards²⁷ and was extensively tested through focus groups and alpha testing, as previously reported.²⁶ Of note, osteoporosis nurses involved in the current trial were not involved in the development of the PDA. Three versions of the PDA were developed depending on the individualized risk of subsequent fracture and the preferred first-line AOM. As an example, the PDA for patients at high risk and eligible for bone anabolics as first-line treatment can be found in **Data S1**. Treatment options included bone-resorption inhibitions comprising the oral bisphosphonates (alendronate or risedronate) and subcutaneous bone-remodeling agents (denosumab) or subcutaneous anabolic agents (teriparatide or romosozumab).

Outcomes

The primary outcome of the study was AOM persistence at 12 months after the first visit to FLS. Secondary outcomes were treatment initiation after the first FLS visit (baseline), AOM adherence at 6 and 12 months, fracture rate, mortality, patients' experiences with the SDM process, and patients' reported decisional conflict. An overview of the primary and secondary outcomes at each follow-up time is provided in the published protocol²⁶ and explained in more detail below. Measures of AOM adherence were calculated using pharmacy-dispensing records for the period between the first FLS visit (medication prescription) and 12-month follow-up.

AOM persistence

Defined as the proportion of patients still in possession of AOM (yes/no) at 12 months after the first visit to FLS. A refill gap of ≥ 4 weeks was used to define non-persistence to AOM, in line with previous studies.³¹⁻³⁴

AOM adherence

Defined as the proportion of time a patient was in possession of AOM—that is, the mean possession rate of AOM (MPR) from the first collection of AOM at the pharmacy shortly following the first FLS visit until the 12-month follow-up. MPR is presented as the percentage of days in possession during the 12 months and as the proportion of patients who were adherent for at least 80% of the 12 months' follow-up (MPR $\geq 80\%$).

Treatment initiation

Defined as the date of first collection of a prescription for an AOM at the pharmacy based on pharmacy-dispensing records.

Aspects of decisional quality were assessed following the first and follow-up (4 months) FLS visit through 2 validated patient-reported outcome-measurement instruments, as follows:

Shared Decision-Making Questionnaire, 9-item (SDM-Q9)³⁵

Assesses the patient's perceived level of participation in the process of making health decisions consisting of 9 questions using a 6-point Likert scale, where 6 indicated the highest extent of perceived SDM during the process. Questions included, for example, whether the osteoporosis nurse and the patient reached an agreement on how to proceed or whether they weighed out the treatment options. Total scores ranged from 0 to 100, where 100 indicates the highest extent of perceived SDM during the decision-making process,³⁶ calculated according to Kriston et al.³⁵

Decisional Conflict Scale (DCS)³⁶

Measures the patients' perceptions on uncertainty in choosing the preferred option, as reflected by the level of feeling uninformed, lack of clarity about personal values and feeling unsupported in decisions. It consists of 16 questions in 5 subscales each to be answered on a 5-point Likert scale, where 5 indicates the highest extent of decisional conflict. The 5 DCS subscales (uncertainty, uninformed, values unclear, unsupported, and ineffective decision) range from 0 to 100, where higher scores were associated with higher decisional conflict.³⁷ A total score lower than 25 is associated with higher likelihood of a successful decision implementation, indicating a lower degree of the patient feeling uncertain, uninformed, unclear about his/her values, unsupported, and feeling to have made an ineffective decision.

Fractures and mortality

Defined as the number of fractures and number of deaths during the trial and collected from patients' clinical records. Fracture types were classified as major fractures (ie, hip, clinical vertebral, proximal humerus, or distal radius fractures) or other fracture types, based on the Major Osteoporotic Fractures classification endorsed by the International Osteoporosis Foundation.³⁸

Contextual factors

Information on the date of osteoporosis diagnosis, index (initial) fracture type, whether the patient underwent surgery for their index fracture, number of medication types (excluding AOM), and the duration between the index fracture and the first FLS visit with the osteoporosis nurse was collected from patients' clinical records. A baseline patient questionnaire included information on the patient's date of birth, sex, highest achieved educational level (categories from lowest to highest: elementary school, lower vocational, pre-vocational secondary, general secondary, secondary vocational, higher vocational education, university), comorbidities, marital status (categories: single, in a relationship which included married and cohabiting people, and other, which included divorced and widowed people), and health literacy. For current comorbidities, the Rheumatic Disease Comorbidity Index (RDCI) was used, including lung disease, cardiovascular disease, hypertension, diabetes, fractures, depression, cancer, gastrointestinal ulcer, and other gastrointestinal disorders. The total RDCI score³⁹ ranges from 0 to 9, where 9 indicated the highest number of comorbidities present. The total number of comorbidities was dichotomized according to its median as a cutoff to allow statistical analysis, which is an approach that has been demonstrated as an appropriate method for dichotomization of comorbidities.⁴⁰ Health literacy was determined using the HLS-EU-Q16 questionnaire, consisting of 16 questions using a 5-point Likert scale, where 1 indicated

extreme ease with the health literacy task described in the question and 5 indicated extreme difficulty. Health literacy was then dichotomized as limited (0–12) and adequate health literacy (13–16).⁴¹ Educational level classification was dichotomized as non-college/non-university level (elementary school–secondary vocational education) and college/university level (higher vocational education–university).⁴²

Sample size

The formula from Chow et al⁴³ was used to calculate the sample size and determine the superiority of MCAI based on AOM persistence, further explained in the published study protocol.²⁶ To obtain a power of 80% with an alpha of 5%, along with the assumption of 43% persistence in UC⁴⁴ and a potential dropout of 10%, 105 patients per group needed to be included. An increase of at least 20% in persistence in the MCAI group compared with the UC group was deemed clinically relevant.⁴⁵

Data analysis

Version 4.3.2 of R Studio was used and a statistician was consulted for the analyses. Baseline characteristics of the UC and MCAI groups were described using descriptive statistics.

To account for missing data in confounders and secondary outcomes, multiple imputation was used according to the method described by van Buuren et al.⁴⁶ Thirty imputed datasets were created and predictive mean matching was used for continuous, polytomous regression for categorical and logistic regression for dichotomous variables. All further statistical tests were performed using the imputed data.

Differences in primary and secondary outcomes between MCAI and UC were first tested using Pearson's chi-square test (AOM persistence [yes/no] at 12 months after the first visit to FLS, AOM adherence, subsequent fracture during trial) and the independent-samples *t* test at baseline and 4 months (SDM-Q9, total DCS score, DCS [subscales]). As pre-post treatment arms could differ in baseline characteristics, multivariable logistic (AOM persistence [yes/no] at 12 months after the first visit to FLS, AOM adherence, subsequent fracture during trial) and linear (SDM-Q9, total DCS score, DCS subscales separately) regression analyses were used to adjust between-group differences for confounders. Potential confounding variables were identified by testing the association of all contextual factors with difference in treatment arms using the independent-samples *t* test or Pearson's chi-square test. As a result, potential confounding factors included the following: (1) time between index fracture and first FLS visit with an osteoporosis nurse, (2) whether the patient indicated to have received lifestyle advice during the FLS visit, (3) whether surgery was performed for the index fracture, and (4) FLS center (MUMC+ or VieCuri). Other contextual factors, such as index fracture type, age, and gender, were univariably not retained as potential confounders.

Post hoc analyses

Between the second visit of participants in the UC group and the start of recruitment of the MCAI group, a new Dutch guideline on AOM treatment and lifestyle management was published and implemented at both FLS centers.³⁰ The guideline included 2 important changes. First, the new information on rebound fractures after denosumab stipulated that a treatment course of denosumab should be followed by 2 intravenous infusions of zoledronic acid. Second, it was recommended to start bone anabolic AOM in patients with grade 2 (25%–40% reduction in vertebral height) instead of only grade 3 (>40% reduction in vertebral height) vertebral

fractures.³⁰ Third, romosozumab was not yet available for prescription during the time that the UC group considered AOM treatment options. Last, it is important to note that, for both teriparatide and romosozumab, an educational and motivational support program is initiated by pharmacy care to improve persistence.⁴⁷ As these changes could have influenced the outcome of the MCAI, drug type was included as a variable in the multivariable analyses and tested for interaction with treatment arm and a post hoc analysis excluded patients who initiated denosumab, teriparatide, or romosozumab as these patients received an educational and motivational support program alongside regular FLS care or would have previously not been prescribed denosumab due to the guideline change. A second post hoc analysis was performed to assess potential differences between participants with limited (0–12) and adequate (13–16) health literacy levels within both the UC and MCAI groups.⁴¹ Of note, the PDA was already based on the latest scientific findings because evidence-based adjustments could already be anticipated.

Process evaluation

The process evaluation of our study²⁶ was conducted according to the method described by Moore et al,^{26,48} addressing 3 components (implementation, mechanisms of impact, and context). The process evaluation was performed using semi-structured individual interviews. Ten patients (5 from each center) were invited after the FLS follow-up visits via telephone by 1 of the researchers of the team. It was ensured that a wide age range of participants would be included. All 4 osteoporosis nurses were invited when all patients in the MCAI arm had completed the FLS follow-up visit.

Themes addressed in patient interviews comprised implementation of MCAI (page by page discussion on whether content was discussed, issues discussed on their AOM initiation and adherence, views on their conversation with the osteoporosis nurse), mechanism of impact (whether patients considered the PDA and conversation with osteoporosis nurse useful and whether all information was understood), and context (whether the osteoporosis nurse had enough time for the patient).

Themes addressed in nurse interviews comprised implementation (to what extent the PDA and motivational interviewing steps were implemented in their consultations and, if not all steps were always followed, elaboration was asked), mechanism of impact (noticeable behavioral changes in patients and noticeable behavioral changes in osteoporosis nurses when using the MCAI), and context (obstacles for the nurse and/or for patient, steps of MCAI that were of lesser value, and overall value of MCAI) (see [Tables S6](#) and [S7](#) for interview questions).

During the interviews, patients were asked to score themes addressed in the interviews by using a 5-point Likert scale. Interviews were documented through field notes and analyzed through subthemes within each interview theme.

Results

In total, 245 patients (MCAI: $n = 136$; UC: $n = 109$) were included between October 2019 and July 2022 (original inclusion deadline was extended due to the COVID-19 pandemic). The flowchart ([Figure 2](#)) presents details on the number of persons invited to participate and finally included in the analyses. In total, 212 of 245 (87%) of those consenting and having any data contributed to results on adherence (see **Figure S1** for information on missing data), and 235 of 245 (95%) had data at baseline and at least 1 follow-up assessment on SDM (see [Table S2](#)). Three months before the 12-month follow-up, 1 patient in the UC group died. However, as this patient had

pharmacy data and completed 2 questionnaires, the patient could therefore be included with death as the endpoint for the persistence data.

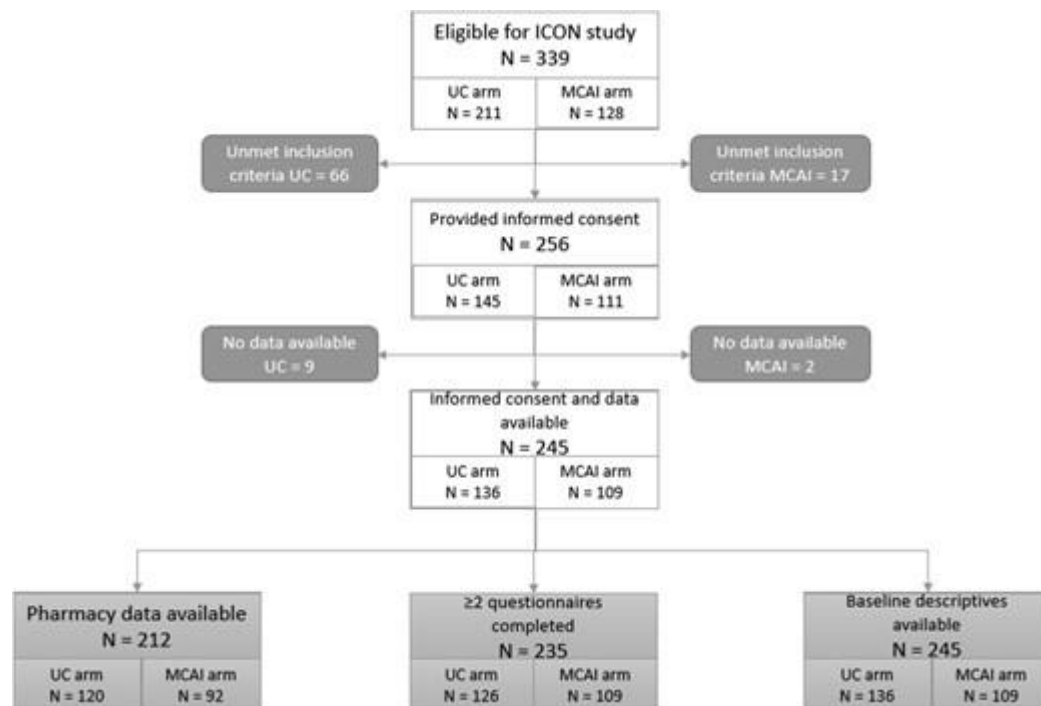


Figure 2

CONSORT flow diagram of the inclusion process. In total, 136 patients were included in the UC group and 109 patients were included in the MCAI group. Among them, 10 patients from the UC group and 2 patients from the MCAI group had only pharmacy data available for the AOM initiation, adherence, and persistence outcomes, lacking questionnaire data for the secondary outcomes SDM-Q9 and DCS. Abbreviations: AOM, anti-osteoporosis medication; CONSORT, Consolidated Standards of Reporting Trials; DCS, Decisional Conflict Scale; MCAI, multicomponent adherence intervention; SDM-Q9, 9-item Shared-Decision-Making Questionnaire; UC, usual care.

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[Table 1](#) presents baseline characteristics of the patients in each treatment group. Across both study groups, the mean age was 71 years and approximately 75% were female. The average time between the index fracture and the first FLS visit was 3.6 ± 2.5 months for UC and 4.1 ± 3.6 months for MCAI.

Table 1

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Crude baseline patients' characteristics and potential confounders for the MCAI and UC groups.

Baseline patient characteristics	UC (n = 136)	MCAI (n = 109)
Age (mean ± SD), y	71 ± 12	71 ± 9
Female, n (%)	101 (74%)	86 (79%)
Ethnicity, n (%)		
Asian Black White Hispanic/Latino Other	1 (1%)0 (0%)135 (99%)0 (0%)0 (0%)	2 (2%)0 (0%)105 (96%)1 (1%)1 (1%)
Education, n (%)		
Non-college/non-university College/university Other (eg, specialized training)	86 (63%)34 (25%)16 (12%)	55 (50%)44 (40%)10 (10%)
Adequate health literacy, n (%)	101 (74%)	76 (70%)
Marital status, n (%)		
Single Relationship (married/cohabiting) Other (divorced/widowed)	11 (8%)100 (74%)25 (18%)	15 (14%)82 (75%)12 (11%)
Fracture type, n (%)		
Major Hip Clinical vertebral Proximal humerus Distal radius Other (eg, ankle, clavicle, phalanges)	78 (57%)15 (19%)29 (37%)13 (17%)21 (27%)58 (43%)	71 (65%)12 (17%)31 (43%)14 (20%)14 (20%)38 (35%)
FLS center, n (%)		

Baseline patient characteristics	UC (n = 136)	MCAI (n = 109)
MUMC+ VieCuri	104 (76%)32 (24%)	59 (54%)50 (46%)
Years since osteoporosis diagnosis, n (%)		
≥7 y 4–6 y 2–3 y 0–1 y	3 (3%)104 (76%)29 (21%)	8 (7%)1 (1%)2 (2%)98 (90%)
RDCI score (Mean ± SD)	2.0 ± 2.0	2.0 ± 2.0
Number of total medications (mean ± SD) Polypharmacy, n (%)	6.0 ± 5.5108 (90%)	7.0 ± 5.890 (98%)
AOM medication type (excluding non-initiators and patients with missing pharmacy data), n (%)		
Bone-resorption inhibitors (alendronate, risedronate) Bone-resorption inhibitor (remodeler) (denosumab) Anabolic agents (teriparatide, romosozumab) Non-initiators Missing pharmacy data	116 (85%)1 (1%)03 (2%)16 (12%)	75 (69%)1 (1%)14 (13%)2 (2%)17 (15%)
Surgery for index fracture, n (%)	35 (26%)	20 (18%)

Total medication refers to the total amount of medication regardless of osteoporosis.

Abbreviations: FLS, Fracture Liaison Services; MCAI, multicomponent adherence intervention; MUMC+, Maastricht University Medical Centre+; RDCI, Rheumatic Disease Comorbidity Index; UC, usual care.

AOM persistence, adherence, and initiation

Overall, 5 patients (MCAI: 2/92; UC: 3/120) did not initiate treatment. Most patients in both groups initiated alendronate (MCAI: 75/92; UC: 113/120) as AOM treatment; other options entailed denosumab (MCAI: 1/92; UC: 1/120), risedronic acid (MCAI: 0/92; UC: 3/120), romosozumab (MCAI: 5/92; UC: 0/120), or teriparatide (MCAI: 9/92; UC: 0/120).

Crude persistence (yes/no) at 12 months after the first visit to FLS was 80.4% for the MCAI group and 76.7% for the UC group (unadjusted difference: 0.23; p -value: .630; adjusted difference: 1.0; 95% CI: 0.5 to 2.2; p = .626) (Table 2). Mean adherence at 12 months was 89.1% and 80.0% for MCAI and UC groups, respectively (unadjusted difference: 1.1; p -value: .302; adjusted difference: 1.3; 95% CI: 0.6 to 2.7; p = .569). The odds ratio greater than 1 illustrates an increased likelihood to be persistent or adherent for those receiving the MCAI opposed to UC. The mean MPR at 12 months was 90.9% and 88.3% for MCAI and UC groups, respectively (unadjusted difference: 1.1; p -value: .270; adjusted difference: 1.7; 95% CI: -4.4 to 7.8; p = .582).

Table 2

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Crude effect of UC and MCAI groups at 6 and 12 months on adherence and adjusted incremental effect of MCAI opposed to following multivariable regression.

Pharmacy data (n = 245)	UC (n = 120)	MCAI (n = 92)	Odds ratio (95% CI) MCAI vs UC	p
Initiation (yes/no)	117 (97.5%)	90 (97.8%)	—	
Persistence (yes/no) at 12 months	92 (76.7%)	74 (80.4%)	1.14 (0.6, 2.1)	.724
Switched medication (yes/no)	8 (6.7%)	3 (3.3%)	—	
Adherence at 12 months (MPR $\geq$ 80%)	96 (80.0%)	82 (89.1%)	1.25 (0.6, 2.7)	.569
			Adjusted mean difference (95% CI), MCAI vs UC	

Pharmacy data (n = 245)	UC (n = 120)	MCAI (n = 92)	Odds ratio (95% CI) MCAI vs UC	p
MPR—1 year (mean ± SD)	88.3% ± 24.1%	90.9% ± 20.4%	1.7 (−4.4, 7.8)	.582
MPR—6 months (mean ± SD)	90.8% ± 21.8%	93.6% ± 17.5%	2.5 (−3.0, 7.9)	.373

Abbreviations: MCAI, multicomponent adherence intervention; MPR, medication possession ratio; UC, usual care.

Other secondary outcomes

The crude SDM-Q9 score was significantly higher at 4 months in the MCAI group compared with the UC group (unadjusted difference: 8.6; *p*-value: .024; adjusted difference = 10.7; 95% CI: 2.8 to 18.7; *p* = .008), where a difference demonstrates a higher mean in the MCAI group compared with UC. The total DCS score did not demonstrate significant results (unadjusted difference: 0.4; *p*-value: .688; adjusted difference = 0.1; 95% CI: −2.8 to 2.8; *p* = .997). The DCS total and subscales showed no significant differences.

In total, 17 of 126 patients (13.5%) in the UC group and 13 of 107 patients (12.1%) in the MCAI group (unadjusted difference: 0.02; *p*-value: .892; adjusted difference = 0.8; 95% CI: 0.3 to 1.8; *p* = .566) sustained a subsequent fracture during the follow-up period (see [Table 3](#)).

Table 3

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Crude effect of MCAI and UC on shared decision-making, decisional conflict, and adjusted incremental effect at the first FLS visit and 4 months afterward from multivariable linear and logistic regressions.

	UC (mean ± SD) (n = 126)		MCAI (mean ± SD) (n = 107)		Odds ratio, baseline (95% CI), MCAI vs UC	p	Odds ratio, 4 months (95% CI), MCAI vs UC
	After first FLS	4 months after first FLS	After first FLS	4 months after first FLS			
Successful decision	57 (45.2%)	59 (46.8%)	40 (37.4%)	48 (44.9%)	1.06 (0.6, 1.8)	.833	0.91 (0.5, 1.6)

	UC (mean ± SD) (n = 126)		MCAI (mean ± SD) (n = 107)		Odds ratio, baseline (95% CI), MCAI vs UC	p	Odds ratio, 4 months (95% CI), MCAI vs UC
	After first FLS	4 months after first FLS	After first FLS	4 months after first FLS			
implementation (DCS ≤25)							
	Baseline	4 months after initial FLS	Baseline	4 months after initial FLS	Adjusted mean difference (95% CI), MCAI vs UC		Adjusted mean difference (95% CI), MCAI vs UC
SDM-Q9 total score	50.1 ± 23.9	39.1 ± 30.0	60.4 ± 22.5	47.7 ± 29.2	10.0 (3.4, 16.5)	.003	10.7 (2.8, 18.7)
DCS total score	23.0 ± 10.9	23.3 ± 9.9	21.7 ± 10.0	23.8 ± 10.5	−1.5 (−4.3, 1.4)	.314	0.1 (−2.8, 2.8)
Uncertainty subscale	24.8 ± 13.7	24.0 ± 12.6	21.9 ± 13.2	25.7 ± 12.8	−3.3 (−7.0, 0.3)	.075	1.0 (−2.6, 4.8)
Uninformed subscale	19.8 ± 14.9	19.7 ± 13.4	19.1 ± 12.4	21.6 ± 13.5	−0.4 (−4.2, 3.4)	.839	1.1 (−2.5, 4.7)
Value unclear subscale	23.5 ± 12.1	28.6 ± 16.3	22.7 ± 11.9	25.4 ± 14.4	−0.9 (−0.1, 0.1)	.605	−3.8 (−8.0, 0.5)
Unsupported subscale	23.5 ± 12.3	25.1 ± 11.7	23.5 ± 11.7	25.0 ± 12.7	−0.6 (−3.8, 2.7)	.733	−0.1 (−3.4, 3.2)
Ineffective decision subscale	23.5 ± 13.8	20.0 ± 12.8	21.4 ± 12.4	21.9 ± 12.4	−2.0 (−5.6, 1.6)	.268	1.3 (−2.2, 4.8)

Abbreviations: DCS, Decisional Conflict Scale; FLS, Fracture Liaison Services; MCAI, multicomponent adherence intervention; SDM-Q9, 9-item Shared Decision-Making Questionnaire; UC, usual care.

Post hoc analyses

The first sensitivity analysis excluded the patients who were prescribed denosumab, teriparatide, or romosozumab (MCAI: $n = 15$; UC: $n = 1$) for analyses of primary as well as secondary endpoints. Results did not change compared with the main analyses (see [Tables S3](#) and [S4](#)).

Post hoc analysis by health literacy revealed significant interactions between treatment arms and health literacy for all primary outcomes and the SDM process at 4 months ([Table 4](#)). The effect of MCAI compared with UC on persistence and adherence was higher in those with adequate health literacy but lower in those with limitations in health literacy (although the effect of MCAI within each health literacy group was not significant). On the other hand, the effect of MCAI on the SDM process at 4 months was significantly higher in persons with health literacy limitations, along with a smaller difference between the first FLS visit and 4 months later compared with patients with adequate health literacy receiving MCAI. Within health literacy groups, the impact of MCAI was significantly higher immediately following the initial visit in the adequate health literacy group but the impact was higher after the follow-up visit at 4 months in those with limitations in health literacy. No differential effect by health literacy was seen on decisional conflict. Differences in patient characteristics between patients with limited and adequate health literacy were not found (see [Table S5](#)).

Table 4

[Open in new tab](#)

Post hoc multivariable linear and logistic regressions analyzing the effect of MCAI effectiveness in limited vs adequate health literacy adjusted for confounding factors.

	Limited health literacy		Odds ratio (95% CI), MCAI vs UC	<i>p</i>	Adequate health literacy	
	UC ($n = 33$)	MCAI ($n = 30$)			UC ($n = 87$)	MCAI ($n = 62$)
Persistence at 12 months (yes/no)	24 (72.7%)	20 (66.6%)	0.63 (0.2, 2.0)	.427	69 (79.3%)	57 (91.9%)
Adherence at 12 months ($\geq 80\%$ MPR)	26 (78.8%)	22 (73.3%)	0.58 (0.2, 2.0)	.398	70 (80.5%)	60 (96.7%)

	Limited health literacy		Adequate health literacy			
	UC (<i>n</i> = 33)	MCAI (<i>n</i> = 30)	Odds ratio (95% CI), MCAI vs UC	<i>p</i>	UC (<i>n</i> = 87)	MCAI (<i>n</i> = 62)
Fracture during trial (yes/no)	7 (21.2%)	2 (6.7%)	0.25 (0.1, 1.4)	.158	10 (11.5%)	11 (17.7%)
DCS ≤ 25 (yes/no)	21 (63.6%)	16 (53.3%)	0.10 (−0.1, 0.2)	.806	38 (43.7%)	32 (1.0%)
	UC (<i>n</i> = 33)	MCAI (<i>n</i> = 30)	Adjusted mean difference (95% CI)		UC (<i>n</i> = 87)	MCAI (<i>n</i> = 62)
MPR (mean)—1 year ^a	87.1% ± 25.0%	84.1% ± 26.7%	−4.9 (−17.8, 8.0)	.446	88.8% ± 23.8%	94.8% ± 16.0%
MPR (mean)—6 months	91.0% ± 21.6%	88.7% ± 25.3%	−5.5 (−17.3, 6.3)	.355	90.7% ± 22.0%	96.9% ± 11.8%
	UC (<i>n</i> = 33)	MCAI (<i>n</i> = 33)	Adjusted mean difference (95% CI)		UC (<i>n</i> = 93)	MCAI (<i>n</i> = 74)
SDM-Q9 score at first FLS visit	40.9 ± 25.9	53.0 ± 24.1	9.8 (−4.0, 23.5)	.161	53.4 ± 22.4	63.6 ± 21.1
SDM-Q9 score at 4 months ^a	28.0 ± 28.7	50.7 ± 28.9	19.7 (4.8, 34.6)	.010	43.2 ± 29.5	46.4 ± 29.5

	Limited health literacy		Odds ratio (95% CI), MCAI vs UC	<i>p</i>	Adequate health literacy	
	UC (<i>n</i> = 33)	MCAI (<i>n</i> = 30)			UC (<i>n</i> = 87)	MCAI (<i>n</i> = 62)
DCS score at first FLS visit	26.6 ± 12.0	25.6 ± 7.9	−2.2 (−7.5, 3.2)	.421	21.7 ± 10.3	19.9 ± 10.4
DCS score at 4 months	22.5 ± 11.7	23.2 ± 9.6	−1.1 (−6.6, 4.5)	.701	25.3 ± 9.0	25.0 ± 11.9
Uncertainty subscale	25.2 ± 14.1	25.5 ± 12.1	−0.1 (−6.8, 6.8)	.997	23.6 ± 12.0	25.8 ± 13.2
Uninformed subscale	20.3 ± 14.6	24.5 ± 12.3	1.9 (−5.1, 8.8)	.596	19.4 ± 13.0	20.2 ± 13.8
Value unclear subscale	31.5 ± 17.5	25.7 ± 13.5	−7.3 (−15.5, 1.0)	.081	27.5 ± 15.8	25.2 ± 14.9
Unsupported subscale	29.1 ± 13.4	25.7 ± 12.2	−2.8 (−9.2, 3.7)	0.398	23.6 ± 10.7	24.7 ± 13.0
Ineffective decision subscale	21.8 ± 14.3	24.1 ± 11.5	1.9 (−4.9, 8.6)	0.583	19.4 ± 12.3	20.9 ± 12.8

Values are average scores.

^aInteraction between health literacy and arms was significant.

Abbreviations: DCS, Decisional Conflict Scale; FLS, Fracture Liaison Services; MCAI, multicomponent adherence intervention; MPR, medication possession ratio; SDM-Q9, 9-item Shared Decision-Making Questionnaire; UC, usual care.

Process evaluation

All 4 osteoporosis nurses and 10 patients (7/10 women with a mean age of 71 ± 8 years) in equal numbers in each FLS were interviewed (see [Table S6](#) for interview results). Most patients (9/10) expressed that the key information of the PDA was discussed during the first FLS visit (implementation), and experienced they were truly involved in the decision to initiate AOM

(see [Table S7](#) for interview results). Seventy percent (7/10) of patients found the PDA beneficial during FLS visits and 90% (9/10) found the conversations with the HCP during the second FLS visit to be useful (mechanism of action). All patients reported a positive SDM experience, highlighting that the HCP dedicated sufficient time during their visitation hour (context).

The implementation of the MCAI by nurses (4/4) was not entirely consistent. In particular, the nurses failed to adhere to the page-by-page discussion of the PDA and systematic execution of the motivational interviewing (implementation). Nurses mentioned that several patients preferred the HCP making the decision or stopped using the PDA as patients became confused. They also mentioned that not all patients benefit from the MCAI as it could sometimes lead to confusion due to either information overload, lower health literacy, or preference for a paternalistic relationship with the HCP. However, when used fully, patients became more proactive, asked more questions, and were more transparent about their preferences, although they also sometimes requested reflection time before making a final decision (mechanism of action). Obstacles for HCPs included limited time (context).

Discussion

This is the first study to incorporate the use of a PDA followed by motivational interviewing in the investigation of AOM treatment persistence, adherence, and decision quality in patients with osteoporosis with recent fracture attending nurse-staffed FLS clinics. Additionally, to our knowledge, this study is the first to provide evidence on SDM in FLS care.

The results of this clinical study, confirming recent literature,¹⁸⁻²⁰ demonstrated no significant effect of MCAI on AOM persistence, adherence, and decisional conflict. This insignificant effect on adherence could potentially be due to the high adherence in the UC group resulting from already well-organized FLS centers. A randomized controlled trial analyzing the effectiveness of a PDA compared with UC in 57 postmenopausal patients with osteoporosis reported similar insignificant results regarding AOM treatment adherence in the intervention arm.¹⁴ The high adherence in the UC group was also confirmed in a Dutch experimental study in patients visiting an FLS and requiring AOM, demonstrating a persistence of 75% in the UC group, and showed that telephone calls did not improve persistence compared with UC.⁴⁹

The impact of SDM tools on the DCS score in patients was not significant, which aligns with other studies.^{11,14} More specifically, our patients in the MCAI group experienced a decrease of 1.1 points in total DCS score compared with patients in the UC group after the first FLS visit. Of note, Sun⁵⁰ found that, for every unit increase in the DCS, people were 59 times more likely to change their minds and 5 times more likely to express decisional regret.

New to the current body of literature are our significant positive effects of MCAI on the SDM process compared with UC in FLS care. Furthermore, the stratification by health literacy provided in-depth information on how patients with different levels of health literacy responded to MCAI. Both health literacy groups demonstrated a significantly higher perception of SDM when receiving MCAI. Patients with limited compared with adequate health literacy demonstrated a significant larger improvement in perceived SDM process 4 months after the first FLS visit, while patients with adequate health literacy demonstrated only a significant improvement of SDM immediately after the first visit. These temporal differences not only provide insights into the immediate impact of MCAI but suggest a more sustained effect of MCAI in those with health literacy limitations. Paradoxically, the positive experience with the SDM

process did not result in better adherence, as patients with limited health literacy who received the MCAI had numerically even a somewhat lower adherence.

The process evaluation demonstrated inconsistent implementation and could therefore further explain the results mentioned above. Nurses highlighted that not all patients benefitted from the MCAI due to either information overload, lower health literacy, or preference for a paternalistic relationship with the HCP. In these cases, nurses should navigate the delicate balance of refraining from insistence and strategically taking a step back while ensuring that patients understand the decision options at hand and possible consequences. While this does not always allow complete application of MCAI, recognizing the resistance as a valid expression of concerns does allow for a more patient-centered approach.

Limitations

This study has several limitations. First, there were some discrepancies in the nature of the FLS visits between the 2 centers. The first visit lasts 40 minutes at MUMC+ and 20 minutes at VieCuri. Nevertheless, no differences between centers were seen in the data. Second, the nature of the trial, being pragmatic and which aimed to evaluate the effectiveness of MCAI in a real-world setting, may have allowed for variability in how MCAI was applied across the FLS centers or by different osteoporosis nurses. This could have affected the consistency of the results. Third, the sample of this study may not be representative of all patients with osteoporosis attending FLS, as individuals who attend FLS may have different characteristics and selection bias may have occurred in both groups. Additionally, as mentioned before, the 2 groups used for comparison in this study might slightly differ due to the possible effect of the COVID-19 pandemic and AOM treatment guideline revision that occurred between the second visit of participants in the UC group and the start of recruitment of the MCAI group.

Consequently, more frequent initiation of romosozumab and teriparatide is expected due to the educational and motivational support program that was offered to these patients. Fourth, stratification based on pharmacy and questionnaire data may have introduced some potential selection bias. Nevertheless, no differences between these patient groups were observed in the data. Last, selection bias could have been introduced in the recruitment of patients for the process evaluation due to the convenience sampling method.

Clinical implementation

To implement the MCAI into the clinic, several points should be considered. First, the PDA should be adapted to other countries based on national management guidelines. Second, nurses should be trained in administering the PDA and motivational interviewing, with emphasis on stimulating interactive communication with the patient. Third, healthcare systems should empower patients to express their needs and preferences and allow open discussion between the HCP and patient on AOM initiation. Fourth, peer-to-peer intervention should routinely be organized to discuss how to deal with hurdles and challenges when implementing the MCAI. Finally, the impact on adherence will be larger when adherence in specific FLS is suboptimal.

Further research should focus on the consequences of offering a comprehensive range of treatment options, including the decision not to initiate treatment, through PDAs. It is crucial to establish whether the use of PDAs improves or possibly hinders patients' comprehension of the information provided, potentially leading to suboptimal decision-making, particularly in cases where osteoporosis is already at a critical stage.

The impact of the effectiveness of MCAI for patients with limited health literacy should also be further investigated. Although no significance in results was found, this study suggests a lower MCAI effectiveness in patients with limited health literacy. Future research should focus on identifying specific components that could improve the effectiveness of MCAI for patients with limited health literacy. Adaptation of the MCAI, such as simplified information presentation or audiovisual aids tailored to the needs of this subgroup, could further improve AOM treatment persistence, adherence, and decision quality, and ultimately promote better osteoporosis management outcomes. Further work of the ICON study will focus on the cost-effectiveness of MCAI and will provide a lifetime horizon via predictive modeling.

Conclusion

The results of this study show a significant positive effect of the introduction of MCAI on the SDM process when compared with UC in FLS care. When experienced nurses administer MCAI in FLS care, its effectiveness on the SDM process appears to be maximized in individuals with adequate health literacy. The absence of a significant effect on adherence in this sample with high adherence in the UC group may preclude final deliberation on the economic value of an MCAI as the study mainly focused on oral bisphosphonates. It would be interesting to gain more insight into the influence of SDM in patients who initiate denosumab and anabolics compared with our MCAI on adherence. Moreover, insight into patient preferences for different AOMs might be valuable information when working on new management guidelines. Currently, patient preferences are not accounted for when evaluating (economic) benefits of interventions or when drafting management guidelines.

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Author contributions

Lieke Maas (Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing—original draft, Writing—review & editing), Mickael Hilgsmann (Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing—review & editing), Caroline E. Wyers (Conceptualization, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing—review & editing), Sandrine Bours (Conceptualization, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing—review & editing), Trudy van der Weijden (Conceptualization, Methodology, Resources, Validation, Writing—review & editing), Joop P. van den Bergh (Conceptualization, Investigation, Methodology, Supervision, Validation, Visualization, Writing—review & editing), Marsha van Oostwaard (Conceptualization, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing—review & editing), Sander M.J. van Kuijk (Conceptualization, Formal analysis, Methodology, Software, Supervision, Validation, Visualization, Writing—review & editing), Annelies Boonen (Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing—review & editing).

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Conflicts of interest

Annelies Boonen received research grants from AbbVie and honoraria for lectures or consultation from Pfizer, Novartis, UCB pharma, AbbVie, and Galapagos, all to her department. Mickaël Hiligsmann received research grants from Radius Health and Angelini Pharma (paid to their institution), lecture fees from Mylan Pharmaceuticals and IBSA (Institut Biochimique SA) (paid to their institution), and was a grant advisor for Pfizer (paid to their institution). The department of Joop P. van den Bergh has received consultancy fees from UCB pharma and Amgen. All other authors declare no conflicts of interest.

Data availability

The data that support the findings of this study are available on request from the corresponding author.

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Supplementary data

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