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ORIGINAL RESEARCH ARTICLE

Labor induction at 41^{+0} gestational weeks or expectant management for the nulliparous woman: The Finnish randomized controlled multicenter trial

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Abstract

Introduction: Neonatal and maternal risks increase in term pregnancy as gestational age advances and become increasingly evident post-term. Management practices of late- and post-term pregnancies vary, and the optimal time point for intervention by labor induction is yet to be determined.

Material and methods: This randomized controlled trial of 381 nulliparous women with unripe cervices compared labor induction at 41^{+0} gestational weeks (early induction) with expectant management and labor induction at 41^{+5} to 42^{+1} gestational weeks (expectant management). This multicenter study included all five university hospitals and the largest central hospital in Finland. The study period was 2018–2022. Participants were randomized to either early induction (48.8%, $n=186$) or expectant management (51.2%, $n=195$) with equal randomization ratios of 1:1. This was a superiority trial, and the primary outcomes were rates of cesarean section (CS) and composite of adverse neonatal outcomes. The trial was registered at the ISRCTN registry (ISRCTN83219789, https://doi.org/10.1186/ISRCTN83219789).

Results: The rates of CS (16.7% [$n=31$] vs. 24.1% [$n=47$], RR 0.7 [95% CI: 0.5–1.0], $p=0.07$) and a composite of adverse neonatal outcomes (9.7% [$n=18$] vs. 14.4% [$n=28$], RR 0.7 [95% CI: 0.4–1.2] $p=0.16$) did not significantly differ between the groups, but the operative delivery rate was lower in the early induction group than in the expectant management group (30.6% [$n=57$] vs. 45.6% [$n=89$], $p=0.003$). The rates of hemorrhage ≥1000 mL and neonatal weight ≥4000 g were also lower in the early induction group, as was the vacuum extraction rate in women with vaginal delivery. Of the women with expectant management, 45.6% ($n=89$) had spontaneous onset of labor. No perinatal deaths occurred, but one case of eclampsia appeared in the expectant management group.

Conclusions: Offering labor induction to nulliparous women at 41^{+0} gestational weeks may decrease the probability of operative delivery, postpartum hemorrhage, and neonatal weight ≥4000 g. However, this study was underpowered to affirm the trends of rising rates of CS and adverse neonatal outcomes in the expectant management group. Thus, expectant management could remain an option for some, as one in two women with expectant management had a spontaneous onset of labor.

KEYWORDS
expectant management, labor induction, late-term pregnancy, post-term pregnancy, prolonged pregnancy

1 | INTRODUCTION

Neonatal and maternal risks increase with advancing gestational age in term pregnancies, especially post-term.[1–5] Studies suggest that labor induction at 41^{+0} gestational weeks or earlier would be beneficial in decreasing the rates of stillbirth and other complications,[6–8] with no increase in the rates of cesarean section (CS) or costs.[5,9–12] In the 2020 systematic review and individual participant data meta-analysis of randomized trials by Alkmark et al. (3 trials, $n = 5161$), labor induction at 41 weeks improved perinatal outcomes compared with expectant management until 42 weeks.[6]

At Helsinki University Hospital, one in three nulliparous women undergoing labor induction for post-term pregnancy had a CS,[13] a rate that can be regarded as rather high. Nulliparous women have a higher risk for CS than multiparous women, and in studies of nulliparous women, comparing labor induction at 39 gestational weeks versus later, the rates of CS were lower in the early induction group compared with expectant management.[14–16] In addition to reducing the rare, but devastating risk of stillbirth, earlier induction could aid in our goal of safely preventing the first CS. This should be a priority in modern obstetrics since the history of a CS poses a risk for maternal and neonatal complications in future pregnancy and labor.[17]

However, in many countries, Finland included, labor induction is started at 41^{+5} to 42^{+1} gestational weeks if the pregnancy has progressed normally.[18] Historically, induced labor has been associated with higher rates of operative delivery and perinatal morbidity than labor of spontaneous onset, and it undeniably tends to require more effort from both the woman in labor and the personnel. However, as one cannot choose to have spontaneous onset of labor at an obstetrically appropriate time, the timing of the possible induction should be carefully assessed to balance the positive and the negative effects.

We aimed to investigate the optimal timing of labor induction in nulliparous late- and post-term women with an unfavorable cervix by comparing labor induction at 41^{+0} gestational weeks (early induction) and expectant management with labor induction at 41^{+5} to 42^{+1} gestational weeks (expectant management). We hypothesized that early induction may reduce adverse labor outcomes and decrease the rate of CS. Although studies on the benefits of earlier induction already existed at the time this study was planned,[7,19,20] earlier induction did not gain popularity in Finland, and hence, a randomized controlled trial was necessary.

Key message

Labor induction at 41^{+0} gestational weeks may decrease the probability of operative delivery when compared with expectant management until 41^{+5} to 42^{+1} in nulliparous women.

2 | MATERIAL AND METHODS

This was a randomized, parallel, superiority multicenter trial carried out in six Finnish hospitals (Helsinki University Hospital, Tampere University Hospital, Turku University Hospital, Oulu University Hospital, Kuopio University Hospital, and Central Finland Central Hospital), together providing care for 6 of 10 deliveries in Finland.[21] The recruitment period was from March 2018 to March 2022.

Pregnant women received information on the study from their primary caregivers or in the hospital antenatal clinics. Those interested in participating contacted the researchers online (Helsinki area) or were referred to the hospital by their primary caregivers (other areas). The study information was available in Finnish; all participants received oral and written information on the study and signed written informed consent. Patients and public involvement was possible by contacting the researchers online through the study website (www.sykeinfo.fi), where additional information on late- and post-term pregnancy, labor induction, and the study protocol was available during the study period.

Inclusion criteria were nulliparity, age ≥18 years, viable singleton pregnancy with a cephalic presentation, no severe fetal malformations detected antenatally, pregnancy dating confirmed by ultrasound in the first-trimester screening at gestational weeks 11^{+0} to 13^{+6}, unripe cervix (Bishop score <6), intact amniotic membranes and no pregnancy complications such as medication-dependent diabetes or pre-eclampsia requiring intervention (labor induction or CS before 41^{+5} gestational weeks). Exclusion criteria were fetal weight

estimation >4500 g or <10%/≤1.5 SD, uterine scar, placenta previa, suspicion of maternal vaginal infection or chorioamnionitis, maternal human immunodeficiency virus, and hepatitis B or C. All women willing to participate visited their antenatal clinic at 41^{+0} gestational weeks to ascertain the mother's and the fetus's well-being. At the screening, all women had a clinical and ultrasound examination, cardiotocography, and pre-eclampsia screening by urine sample and blood pressure measurement.

All participating women were randomized for the date of labor induction at 41^{+0} gestational weeks using a custom-made online randomization site with randomly selected block sizes of five, 10, and 20, with equal randomization ratios of 1:1. The final number of randomizations in the study was 414, of which 206 were for the early induction group and 208 for the expectant management group. Figure 1 shows the formation of the study population.

The intervention group began labor induction the same day (early induction) and the control group was managed expectantly until 41^{+5} gestational weeks (expectant management), that is, managed by the current protocol for late-term pregnancy in Finland. Women in the expectant management group had labor induction at 41^{+5} to 42^{+1} gestational weeks (late induction) if they had not experienced a spontaneous onset of labor or earlier if they had any concerns regarding the safety of continuing expectant management. The method of labor induction was also randomized to three treatment arms: balloon catheter, oral misoprostol, or concurrent use of balloon catheter and misoprostol, with equal randomization ratios of 1:1:1. The different methods were not assessed in this article. After cervical ripening, labor induction was continued by artificial rupturing of the membranes and intravenous oxytocin infusion. No blinding was possible due to the nature of the study.

The primary outcomes were the rates of CS and a composite of adverse neonatal outcomes defined as one or more of the following: Apgar score <7 at 5 min, umbilical artery pH ≤7.05, base excess ≤12.0, and neonatal intensive care unit admission. The secondary outcomes were maternal hemorrhage ≥1000 mL, manual removal of a retained placenta, anal sphincter injury, and intra- or postpartum infection (having two or more of the following: maternal fever ≥38°C, fetal tachycardia, purulent discharge, uterine tenderness,

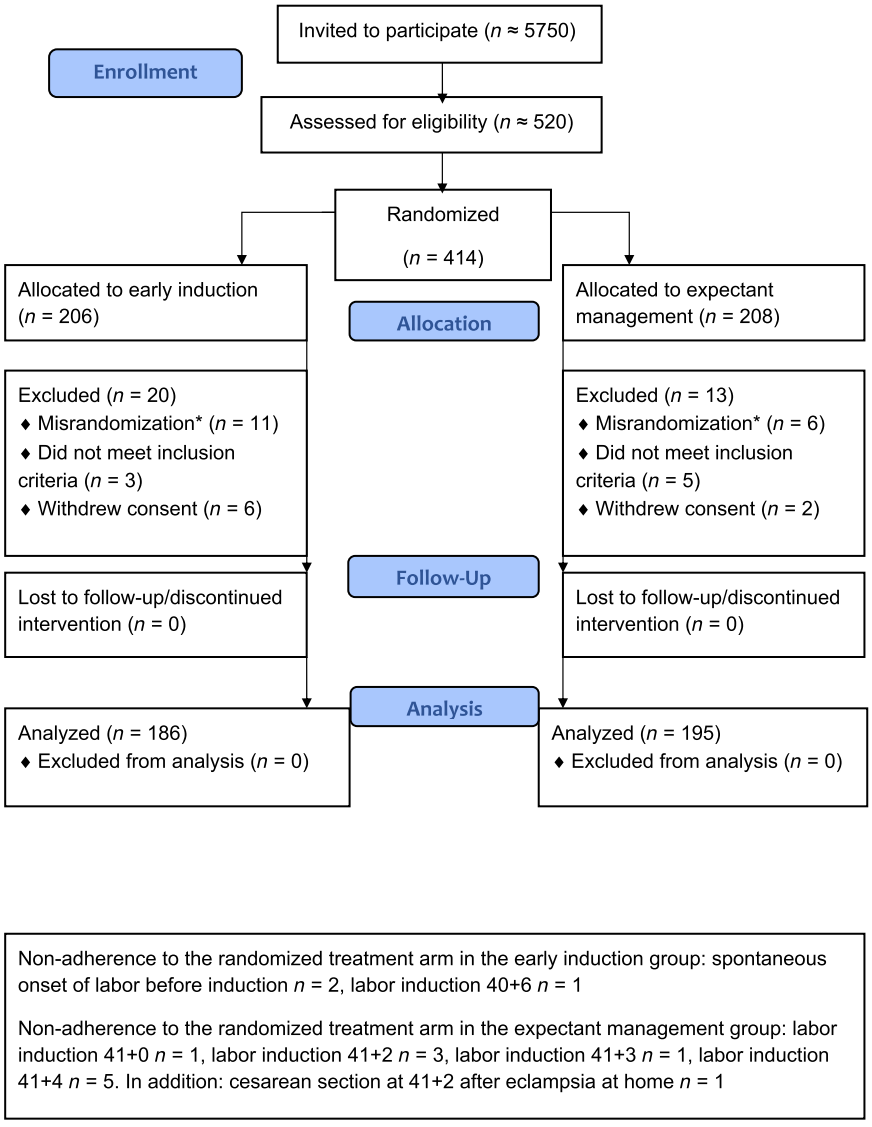

FIGURE 1 Study population.

white cell count ≥20 ×E9/l). The outcomes were followed until discharge from the hospital.

2.1 | Statistical analyses

Our recruitment target was 400 women. This was based on an estimate of a 40% reduction in the CS rate from ~38% (the rate in nulliparous women with labor induction for post-term pregnancy) to ~20% (the overall rate in nulliparous women in Finland),[13,21] requiring a sample of 198 women (significance level 0.05, power 80%). As some women would have spontaneous onset of labor, this figure was doubled to form the target.

We analyzed all data using IBM SPSS for Windows (version 27). To assess the safety of the continuation of the study,[5] we performed an interim analysis halfway through our recruitment target (November 2019). The data were analyzed primarily as intention-to-treat. In addition, we performed exploratory nonpredefined analyses on the primary outcomes, where only women strictly following study protocol for the initiation date of labor induction and women undergoing spontaneous onset of labor before their scheduled late induction were included. For the comparison of categorical variables, we used the chi-square test and Fisher's exact test when appropriate. For continuous variables, we used the *t*-test when the data followed a normal distribution and the Mann–Whitney U test when it did not. We present the results of our primary outcomes using risk ratios (RR) with 95% confidence intervals (CI). A *p*-value < 0.05 was considered statistically significant.

3 | RESULTS

A total of 381 women were included in the study; 186 (48.8%) were in the early induction group and 195 (51.2%) were in the expectant management group (Figure 1). Table 1 shows the characteristics of the study population.

Table 2 presents the delivery outcomes. The CS rate was 16.7% in the early induction group and 24.1% in the expectant management group (RR 0.7 [95% CI: 0.5–1.0], $p=0.07$). The rate of operative delivery was lower in the early induction group compared with the expectant management group (30.6% vs. 45.6%: RR 0.7 [95% CI: 0.5–0.9], $p=0.003$), and of the women with vaginal delivery, the rate of operative delivery by vacuum extraction was lower in the early induction group compared with the expectant management group (16.8% vs. 28.4%, $p=0.02$). The rate of hemorrhage ≥1000 mL was also lower in the early induction group compared with the expectant management group (Table 2) and overall, in women with vaginal delivery compared with CS (13.1% vs. 30.1%, $p<0.001$). The rates of manual removal of a retained placenta, anal sphincter injury, and maternal infection were similar (Table 2). One woman in the expectant management group had eclampsia.

The rate of adverse neonatal outcome was 9.7% in the early induction group and 14.4% in the expectant management group (RR 0.7 [95% CI: 0.4–1.2], $p=0.16$) (Table 2). No perinatal deaths occurred. No difference in mean neonatal weight was seen, but more neonates weighed ≥4000 g in the expectant management group (Table 2). The women with early induction delivered 4 days sooner than the women who were managed expectantly (median 41^{+1} [IQR 0.14] vs. 41^{+5} [IQR 0.43] gestational weeks, $p<0.001$).

In the expectant management group, 89 of 195 women (45.6%) had spontaneous onset of labor. In the exploratory analyses where only women strictly following study protocol for the initiation date of labor induction and women undergoing spontaneous onset of labor before their scheduled late induction were included ($n=367$), 16.4% ($n=30/183$) of the women who underwent labor induction at 41^{+0} had CS, and 12.4% ($n=11/89$) of the women with spontaneous onset of labor between 41^{+1} and 41^{+5} gestational weeks had CS ($p=0.38$). The women in the expectant management group who underwent late induction at 41^{+5} to 42^{+1} had the highest rate of CS, 34.7% ($n=33/95$) ($p<0.001$), in comparison with either early induction or spontaneous onset. The rate of adverse neonatal outcome in these exploratory analyses was 9.8% ($n=18/183$) if labor was induced at 41^{+0} and 12.4% ($n=11/89$) if labor started spontaneously between 41^{+1} to 41^{+5} ($p=0.53$). If labor was induced between 41^{+5} and 42^{+1}, the rate of adverse perinatal outcome was 17.9% ($n=17/95$, $p=0.30$ compared with spontaneous onset).

4 | DISCUSSION

The rates of CS and adverse neonatal outcomes were not statistically different between the groups. However, labor induction at 41^{+0} gestational weeks seems beneficial in reducing the rate of operative deliveries, as seven of 10 women in the early induction group achieved spontaneous vaginal delivery compared with five of 10 in the expectant management group. Also, of the women with vaginal delivery, vacuum extraction was needed in nearly one in three women in the expectant management group but only in one in six women in the early induction group. In addition, fewer women in the early induction group had hemorrhage ≥1000 mL, perhaps explained by the trend of rising CS rates in the expectant management group. Also, women in the expectant management group more often delivered a neonate weighing ≥4000 g, presumably due to the four-day difference in gestational age at delivery.

In the exploratory analyses, early induction and spontaneous onset of labor between 41^{+1} and 41^{+5} gestational weeks seemed equal considering the mode of delivery. Labor induction at 41^{+5} gestational weeks onwards seemed to be the unfavorable option as the rate of CS was highest among the women undergoing late induction compared with women who either had early induction or spontaneous onset of labor. In our opinion, knowing the risks of prolonged pregnancy, offering early induction to all nulliparous women could be considered.

In our study, if early induction had been offered to all, one case of eclampsia could possibly have been avoided. This woman, screened for blood pressure, proteinuria, and symptoms of

TABLE 1 Characteristics of the study population of nulliparous women with unripe cervices, intention-to-treat analyses ($N = 381$).

	Early induction		Expectant management		
	$n = 186$	48.8%	$n = 195$	51.2%	p-value
Age, years (mean, SD)	28.4[a]	4.98	28.8	5.2	0.43
Prepregnancy body mass index, kg/m^2 (median, IQR)	24.4[a]	6.5	25.1[b]	5.4	0.28
Maternal medical condition related to pregnancy	25	13.4	32	16.4	0.42
Gestational diabetes (diet controlled)	20	10.8	24	12.3	0.64
Mild hypertension (not requiring intervention)	2	1.1	5	2.6	0.45
Fear of childbirth (requiring additional support during pregnancy)	3	1.6	6	3.1	0.50
Group B Streptococcus—positivity	39[c]	21.0	39[d]	20.0	0.70
Fetal weight estimation by ultrasound at 41^{+0}, g (mean, SD)	3692.3[e]	304.6	3681.6[f]	322.8	0.74

Note: a, missing data $n = 2$; b, missing data $n = 3$; c, missing data $n = 34$; d, missing data $n = 28$; e, missing data $n = 1$; f, missing data $n = 5$.

Abbreviation: IQR, interquartile range; SD, standard deviation.

pre-eclampsia at the initial visit at 41^{+0} gestational weeks showed no signs of pregnancy complications, and proteinuria was detected only after the CS at 41^{+2} gestational weeks after eclampsia at home. This effect of reducing the rates of pre-eclampsia, gestational hypertension, and eclampsia by early induction has also been seen in previous studies.[5,16]

Although early induction seems a reasonable management option for late-term pregnancy, expectant management should not be abandoned completely. In studies of women's perceptions of their prolonged pregnancy, many experience passing their due date as stressful and may wish for their labor to be induced.[22,23] Some women may, on the contrary, wish for nonmedicalized labor and hope to avoid labor induction.[22] In our study, one in two women in the expectant management group had spontaneous onset of labor. In the exploratory analyses, these women had the lowest rate of CS, 12.4%, although the difference to 16.4% in women in the early induction group was not statistically significant. Predicting the probability of spontaneous onset of labor is difficult and research on the subject is needed,[24] but in our opinion, cervical status at the screening visit may serve as a useful basis for discussion with the pregnant woman.

The strengths of our study included the clinically relevant study setting, which aimed to compare the current treatment protocol used in Finland (expectant management) to one used in some other countries (early induction). The multicenter setting of the study can also be regarded as a strength since this study represented all five university hospitals and the largest central hospital in Finland. However, the multicenter setting also led to some discrepancies in randomization and data collection, which is a weakness of the study. An important strength was our study website in which all information on the study was available for all interested in the study, professionals, and participants alike. This allowed the spreading of accurate information on the topic of late- and post-term pregnancy and labor induction to a wide audience and allowed patient involvement by the possibility of contacting the researchers online for more information.

The number of women recruited can be seen as a weakness although our primary outcome of no increase in the rate of CS by early induction was apparent and we saw a reduction in operative deliveries in the early induction group. However, our conclusion of no statistical difference in the rates of CS and adverse neonatal outcome may be due to inadequate sample size: a 44.3% higher rate of CS (24.1% vs. 16.7%, $p = 0.07$), and a 48.5% higher rate of adverse neonatal outcome (14.4% vs. 9.7%, $p = 0.16$) in the expectant management group may also be concluded. Overall, the CS rates were lower in our study population than estimated by the a priori power calculation. After an interim analysis of our data, our aim was indeed to pursue a larger number of participants. Unfortunately, the COVID-19—pandemic and some organizational changes in the participating hospitals negatively affected our ability to recruit women in the planned, albeit once prolonged, period registered. In the post hoc power calculations, the sample size should have been 1042 women (significance level 0.05, power 80%).

The study's weaknesses include the recruitment method, as many participants needed to contact the researchers themselves to be screened for the study. This may have led to an overrepresentation of active, knowledgeable women causing a healthy volunteer bias, thus impairing the generalizability of the study. In future trials, emphasis on the universal recruitment of all potential and willing women should be a priority. We also regret deficiencies in the exact Bishop score data at the 41^{+0} screening visit. Not

TABLE 2 Delivery outcomes, intention-to-treat analyses ($N = 381$).

	Early induction		Expectant management		
	$n = 186$	48.8%	$n = 195$	51.2%	*p*-value
Maternal outcomes					
Oxytocin use in labor induction or augmentation	142	76.3	140	71.8	0.31
Epidural or spinal analgesia	166[a]	92.2	168[b]	91.3	0.75
Vaginal delivery	155	83.3	148	75.9	0.07
Spontaneous vaginal delivery	129	83.2	106	71.6	0.02
Vacuum extraction	26	16.8	42	28.4	0.02
Cesarean section	31	16.7	47	24.1	0.07
Fetal distress	6	19.4	12	25.5	0.53
Failed induction	10	32.3	14	29.8	0.82
Labor arrest in I stage of labor	7	22.6	12	25.5	0.77
Labor arrest in II stage of labor	6	19.4	7	14.9	0.61
Other	2[c]	6.5	2[d]	4.3	0.67
Hemorrhage ≥1000 mL	22[e,g]	12.2	38[f,h]	20.8	0.03
Hemorrhage ≥1000 mL in vaginal delivery	16[e]	10.6	22[f]	15.8	0.19
Hemorrhage ≥1000 mL in cesarean section	6[g]	20.7	16[h]	36.4	0.15
Manual removal of a retained placenta	5	2.6	7	3.6	0.62
Anal sphincter injury	5	2.7	10	5.1	0.22
Intrapartum infection	6	3.2	8	4.1	0.79
Postpartum infection	8	4.3	15	7.7	0.17
Neonatal outcomes					
Female	89[i]	48.6	95 [j]	49.2	0.91
Adverse neonatal outcome	18	9.7	28	14.4	0.16
Apgar 5 min <7	4	2.2	9	4.6	0.19
Umbilical artery pH ≤7.05	5[k]	2.9	3[l]	1.7	0.45
Umbilical artery BE ≤−12.0	7[m]	4.1	4[n]	2.3	0.35
Neonatal intensive care unit admission	11	5.9	21	10.8	0.09
Neonatal weight, g (mean, SD)	3691°	345	3756°	441	0.11
Neonatal weight ≥4000 g	31°	16.8	57°	29.5	0.004

Note: a, missing data $n = 6$; b, missing data $n = 11$; c, of which paravaginal hematoma $n = 1$, umbilical cord prolapse $n = 1$; d, of which eclampsia at home 41^{+2} gw $n = 1$ and fear of childbirth $n = 1$; e, missing data $n = 6$; f, missing data $n = 12$; g, missing data $n = 2$; h, missing data $n = 3$; i, missing data $n = 3$; j, missing data $n = 2$; k, missing data $n = 14$; l, missing data $n = 21$; m, missing data $n = 17$; n, missing data $n = 24$; o, missing data $n = 2$.

including women with prior deliveries or ripe cervices can also be seen as a weakness. Hence, this study does not aid in elaborating on the guidelines for managing the late-term pregnancies of these women.

5 | CONCLUSION

The rates of CS and a composite of adverse neonatal outcomes were not statistically different, although insufficient sample size to determine favorable numbers in the early induction group may also be interpreted. However, offering labor induction to nulliparous women at 41^{+0} gestational weeks may be beneficial in decreasing the risk of operative delivery, postpartum hemorrhage, and neonatal weight ≥4000 g. Expectant management could, the information offered and if the preference of the parturient, remain a choice for some as one in two women with expectant management had spontaneous onset of labor.

AUTHOR CONTRIBUTIONS

The conception of the study was done by LR, HK, KP, AT, and SH. LR, HK, KP, AT, SH, KV, M-RO, MV, JU, KT, KR, and KM planned and carried out the study. KP analyzed the data and wrote the first manuscript draft supported by HK and LR. All authors participated in the revision process of the manuscript and approved the final version.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ETHICS STATEMENT

The Ethics Committee of the Hospital District of Helsinki and Uusimaa (March 16, 2017: HUS/1978/2016) and the participating hospitals' institutional review boards approved the study. The study protocol is registered in the ISCTN registry (October 10, 2017: ISRCTN83219789, https://doi.org/10.1186/ISRCTN83219789, initial participant enrollment 4/3/2018). All participants received oral and written information on the study and signed written informed consent.

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