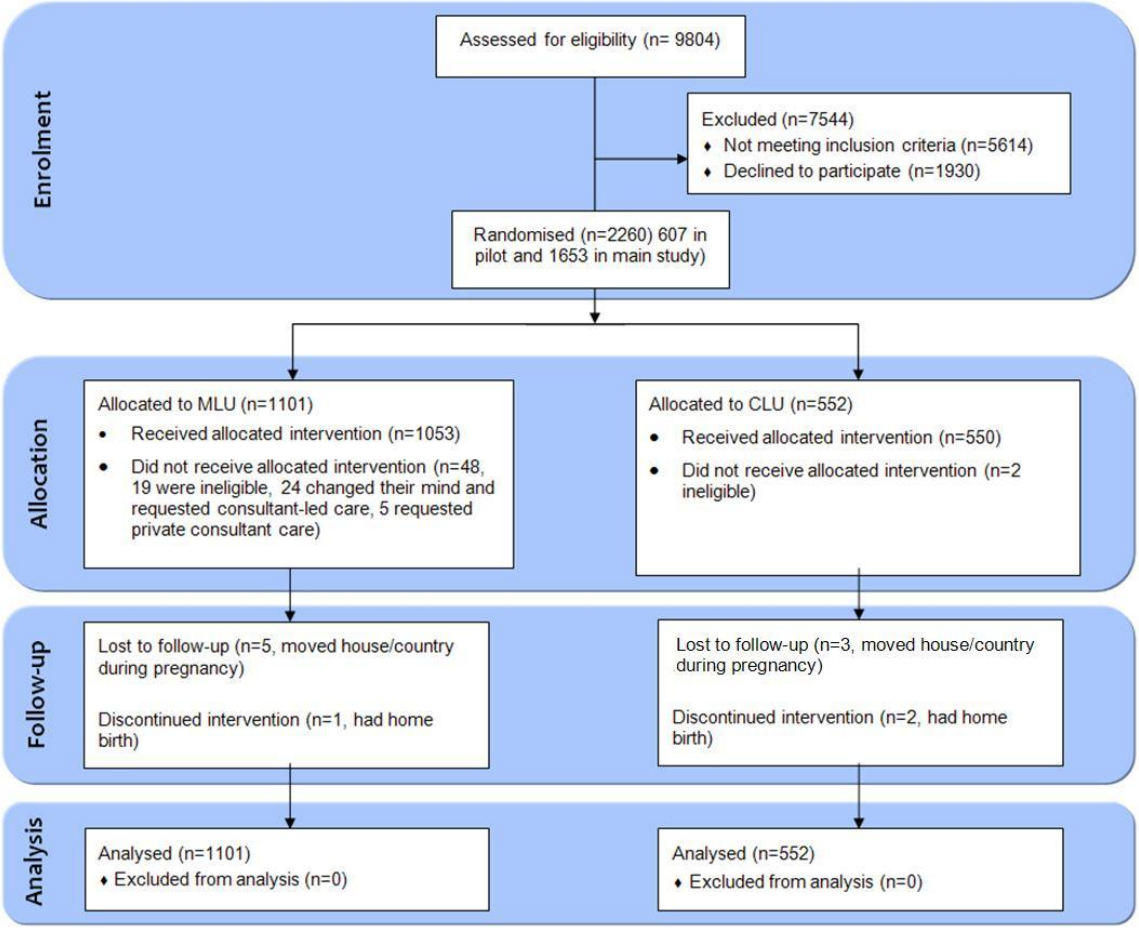
Enrolment
Assessed for eligibility (n= 9804)
Excluded (n=7544)
♦ Not meeting inclusion criteria (n=5614)
♦ Declined to participate (n=1930)
Randomised (n=2260) 607 in pilot and 1653 in main study)
Allocation
Allocated to MLU (n=1101)
• Received allocated intervention (n=1053)
• Did not receive allocated intervention (n=48, 19 were ineligible, 24 changed their mind and requested consultant-led care, 5 requested private consultant care)
Allocated to CLU (n=552)
• Received allocated intervention (n=550)
• Did not receive allocated intervention (n=2 ineligible)
Follow-up
Lost to follow-up (n=5, moved house/country during pregnancy)
Discontinued intervention (n=1, had home birth)
Lost to follow-up (n=3, moved house/country during pregnancy)
Discontinued intervention (n=2, had home birth)
Analysis
Analysed (n=1101)
♦ Excluded from analysis (n=0)
Analysed (n=552)
♦ Excluded from analysis (n=0)