This was a two-arm community cluster randomised non-inferiority trial carried out in 3 woredas (districts) in Southern Nations, Nationalities, and Peoples' Region (SNNPR) in Ethiopia. Clusters, defined by health centre (the referral centre and practical training institution for HEWs where their services are coordinated), were randomised into either the conditional or universal follow-up arm. All children seeking care from the health posts in these clusters were potential recipients of the interventions, in addition to having access to routine care available from private and public health services. Caregivers of children who met the inclusion criteria (fever with a negative malaria rapid diagnostic test (mRDT), and in whom the HEW did not diagnose pneumonia, diarrhoea, or identify other symptoms requiring referral on Day one) were counselled to either: 1) return on Day three (universal arm) or 2) return if symptoms persist (conditional arm). Caregivers in both arms were advised to return or go to the health centre immediately if danger signs developed. Of 25 included clusters, 13 were randomised to the universal follow-up arm and 12 to the conditional follow-up arm. Study Setting The Government of Ethiopia has deployed over 42,000 female Health Extension Workers (HEWs) to provide preventive, promotive, and curative health services at community level; since 2010, the full integrated management of newborn and childhood illness (IMNCI) package has been scaled up in most regions of the country. There are typically two HEWs assigned to a health post in a sub-district with a population of 3,000-5,000 per post; they are supported by the Health Development Army (HDA), female volunteers who enhance community engagement and encourage use of maternal and newborn health services. While IMNCI recommends conditional follow-up, HEWs and their supervisors report a range of other practices for children with unclassified fever, including universal follow-up advice, immediate referral to health centres, or treatment with antimalarial tablets. Participants Children aged 2-59 months who presented to the HEWs in the study area with fever (more than 37.5 degrees Celsius) or a history of fever, a negative malaria rapid diagnostic test (mRDT), no pneumonia or diarrhoea according to IMNCI criteria, and no danger signs were eligible to participate in the study. Written informed consent was obtained from each caregiver before enrolment in the study. Randomisation and masking Cluster randomisation was at the health centre level; the 25 study health centres had an average of 5 health posts and 7.5 HEWs each. Restricted randomisation, where health centre area estimates were balanced on 1) population size, 2) prior 6-month likelihood of mRDT-negative febrile children (number of children mRDT negative/under-five population), and 3) geographic distance from HEW to zonal referral hospital, was performed to minimise the difference between conditional and universal arms. Sorting of clusters and random selection of schemes were carried out in STATA 13 (STATA Corp, College Station, TX, USA). Procedures HEWs collected data on enrolment (Day 1) using an ODK Collect (Open Data Kit Collect version 1.9.1) data collection form on mobile phones, including date of enrolment, a unique child identifier code and clinical indicators such as fever (axillary temperature more than 37.5 centigrade or, if a functional thermometer was unavailable, hot to touch reported by HEW or caregiver reported fever in past two days), cough, respiratory rate, diarrhoea, and danger signs). The enrolment data was synchronized with a server accessed by a data manager for scheduling of follow-up visits. Six independent evaluators (IE), with Bachelor's degree in a health related discipline, clinical experience using IMNCI, a minimum of two years' research experience, and who were able to communicate in Amharic and English, were trained for two days in study procedures and in follow-up of enrolled children. Each district was assigned two IEs, who were blinded to the cluster allocation of the children they were re-assessing. In the conditional follow-up arm, HEWs counselled caregivers on how to detect danger signs and to seek care immediately at the health centre if danger signs developed or the illness worsened, how to reduce fever using paracetamol, and the need to return at any point to the HEW for re-assessment if symptoms persisted or deteriorated. In the universal arm, caregivers were counselled on all of the above, as well as the need to return on Day three to the HEW for a follow-up assessment, even if the child had recovered. Caregivers in both arms were informed that a follow-up home visit would take place by an IE. Clinical outcomes were assessed by an IE during a home visit on Day seven; if the child had not fully recovered, they were assessed again by the IE at Day 14 and, if still not recovered, at Day 28. Caregivers of all children were followed up by phone call to main caregiver to assess vital status (alive/dead) on Day 28. Management of illness at any follow-up visit (i.e. return to HEW on any day, including scheduled assessments) followed national IMNCI guidelines. IEs initially used ODK to collect re-assessment data on enrolled children; half-way through the study the data collection software was changed to CommCare (version 2.38.1, Dimagi, Cambridge, MA), which allowed for automatic linking of follow-up forms, as well as scheduling of subsequent visits, once the children were registered in the Day seven form. The system change reduced the effort of having to manually linking these forms using a child identifier, as well as supported the IEs in tracking the follow-up visits that were due. The data collected during the household follow-up visits included the unique child identifier code, clinical data, additional antimicrobial treatment, hospitalisation, care-seeking history, and costs, as well as caregiver and household characteristics. For children who were brought back on Day three for reassessment in the universal follow-up arm and for any spontaneous re-visit in both arms, a full re-assessment was done by the HEW. If the child still had unclassified fever and a negative mRDT on re-assessment, the child was referred to the nearest health centre, as recommended in the national IMNCI guidelines. A rigorous monitoring system implemented by the study team was part of the continuous quality assurance. The data manager reviewed forms submitted to the server daily, and checked for duplicates, completeness, and accuracy before storing them in the project database. Discrepancies, overdue follow-up visits, and other issues were resolved by phone calls to the IEs and during weekly supervision meetings with field research staff. Biweekly field supervision visits to all HEWs were carried out, and district HEW supervisors were trained to monitor HEW trial activities during routine weekly group supervisions. While the protocol stated a minimum of 10 percent of all enrolled cases and 50 percent of children with treatment failure should have a quality control re-assessment by a research assistant, the actual percentage was significantly higher. Six months into the trial all HEWs and their district supervisors had a refresher training in study procedures. In addition, the regional ethical clearance committee members did a field supervision visit during implementation of the project in all three districts selected for the study (9 health posts; three from each of the arms), which provided feedback recommendations to the study team. The final data set was analysed in STATA 13 (STATA Corp, College Station, TX, USA).