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Factors associated with all-cause mortality and morbidity of motorcycle crash-related neurological and musculoskeletal injuries in Uganda: the MOTOR cluster randomised trial ancillary study

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ABSTRACT

Introduction This study examined the factors linked to all-cause mortality and morbidity from neurological and musculoskeletal injuries during motorcycle accidents in Uganda.

Methods The study was part of a two-armed, parallel, multi-period, cluster-randomised controlled trial of 1003 motorcycle crash victims. Morbidity was assessed using various scoring systems, and mixed effects regression models were employed for analysis.

Results Ninety-day all-cause mortality was 9.2% (82/887). Factors associated with mortality included referral-to-dispatch >1 hour (OR 4.215 (1.802–9.858), p=0.001), Kampala Trauma Score (KTS) ≤6 (OR 7.696 (1.932–30.653), p=0.004), GCS 9–12 (OR 3.432 (1.194–9.870), p=0.022), GCS ≤8 (OR 6.919 (2.212–21.645), p=0.001), intra-axial lesions (OR 78.647 (9.871–626.587), p<0.001), extra-axial lesions (OR 11.933 (1.386–102.750), p=0.024), skull fracture (OR 11.366, (1.197–107.977), p=0.034) and craniotomy (OR 0.260 (0.095–0.706), p=0.008).
A percentage of 14.5% had unfavourable Glasgow Outcome Scale (1–3); associated factors included increasing age (OR 1.02 (1.013–1.045, *p*<.001), multiple injuries (OR 4.559 (1.185–17.531), p=0.027), KTS 7-8 (OR 2.755 (1.285–5.906), p=0.009), KTS ≤6 (OR 7.551 (2.815–20.255), p=0.001), GCS 9-12 (OR 4.07 (1.901–8.719), p=0.001), GCS ≤8 (OR 13.779 (5.643–33.645), *p*<0.001) and craniotomy (OR 0.149 (0.075–0.295), *p*<0.001).
Factors associated with unfavourable patient-reported musculoskeletal outcomes included being married (OR 1.984 (1.322–2.976), *p*=0.001), multiple injuries (OR 1.762 (1.001–3.100), *p*=0.049) and enrolment after the onset of the COVID-19 pandemic (OR 2.095 (1.199–3.659), p=0.009].

Conclusions The key determinants of mortality and adverse neurological and musculoskeletal injury outcomes observed in this study are essential for establishing core outcome sets in future research and predictive models.

Trial registration number Pan African Clinical Trial Registry (PACTR202308851460352).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Motorcycle crashes in low- and middle-income countries represent significant public health issues, exacerbated by low helmet usage and insufficient trauma care resources.

WHAT THIS STUDY ADDS

⇒ This MOTOR trial ancillary study investigated factors associated with all-cause mortality and morbidity from motorcycle crashes, emphasising neurological and musculoskeletal injuries as critical targets for enhancing rural trauma care systems.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our findings indicate that the anatomical nature, multiplicity and severity of injuries, referral-dispatch intervals, operative interventions and COVID-19-related social conditions significantly influenced injury outcomes. These factors may serve as a foundational outcome set for benchmarking future clinical trials and trauma registries.

INTRODUCTION

Motorcycle crashes represent a major global public health challenge, with associated injuries affecting both high-income and low-income countries (LICs).[1] These accidents account for nearly half of emergency department admissions following road traffic incidents.[2] The resulting injuries often involve neurological damage or musculoskeletal trauma, with vulnerable road users such as riders, passengers and pedestrians being impacted disproportionately.[3] Traumatic brain injuries (TBIs) from motorcycle crashes lead to a mortality rate of 3–6%, with higher rates among non-helmet users.[4] Survivors may experience substantial disability and financial burden.[5]

In low- and middle-income countries (LMICs), especially Africa, motorcycle crash-related injuries result in higher mortality and morbidity compared with high-income countries (HICs).[2 3] Factors include lower helmet usage (30.6% in Africa compared with a global average of 44.8%)[1 2] and inadequate road safety legislation.[6] The continent's high commercial motorcycle usage, driven by a favourable climate, exacerbates the problem. Additionally, limited access to post-crash care,

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due to a shortage of skilled healthcare workers and a weak prehospital system, worsens injury outcomes.[7] Africa has only 0.15 neurosurgeons per 100 000 people, far below the WHO recommendation.[8]

Uganda, a low-income country, has a low helmet wearing rate of 19%[1] and faces a high burden of fatal motorcycle crashes, especially on rural low-capacity roads.[9] The inefficiency of the rural trauma care system, long transport distances and ineffective referral protocols worsen injury outcomes.[10] Recognising local factors affecting injury outcomes and barriers to post-crash care is essential for reducing negative impacts. Prior research has often combined all road traffic crash outcomes, neglecting the specificities of motorcycle incidents.[11] This study examined factors related to 90-day mortality and morbidity of neurological and musculoskeletal injuries in motorcycle accidents, which are crucial for improving trauma care in Uganda,[12] and critically reviewed the findings in comparison to the existing global randomised clinical trials.

METHODS

This study was nested within a larger cluster randomised trial which assessed the impact of rural trauma team development on outcomes of motorcycle-crash related injuries at both individual and cluster levels (Pan African Clinical Trial Registry: PACTR202308851460352). The parent trial was a two-armed, parallel, multi-period, cluster-randomised controlled trial of 1003 motorcycle crash victims (501 intervention, 502 control) enrolled at three intervention and three control trauma centres in Uganda.[9] Frontline trauma care providers in the intervention group participated in the fourth edition of Rural Trauma Team Development Course (RTTDC) training of the American College of Surgeons, in conjunction with the establishment of rural trauma networks of first responders, in contrast to the control group.[9] This training intervention, conducted by specialist surgeons and surgery residents, emphasised technical skills in trauma care, including the systematic execution of trauma evaluation and resuscitation. Additionally, the training addressed non-technical skills pertinent to trauma care, emphasising trauma team leadership, trauma coordination, timely decision-making regarding transfer of injuries that exceed local capacity and resource optimisation in rural trauma environments.[10] Clusters were randomly assigned 1:1 using permuted block codes, assuming equal cluster sizes. Participants and outcome assessors were blinded to the allocation. The present ancillary study utilised trial participants' data on covariates collected from the motorcycle trauma outcome registry (MOTOR) project, which was executed in parallel to the trial.[9] The data were collected during August 2019 to August 2023, and the analyses were completed in Spring 2024. The results were reported according to the CONSORT extension guidelines for cluster-randomised trials.[13]

Study settings

The study was conducted in six level III trauma centres including Jinja, Hoima, Fort Portal, Mubende, Kiryandongo and Kampala International University Teaching Hospitals. All referrals were managed at Mulago Hospital in Kampala, Uganda, which is the country's comprehensive level I trauma centre. The level of specialised care and detailed patient work flow processes employed at these facilities has been comprehensively described in prior literature.[9 10]

Eligibility criteria

The clusters were tertiary teaching hospitals that offered 24/7 specialised emergency surgical services. The study population comprised patients aged 2 to 80 years who presented to six sites within 24 hours of a motorcycle crash-related injury. Women who were pregnant, individuals who were mentally incapacitated to provide consent and patients with stroke were excluded to limit reported morbidity to trauma.

Sample size determination

There were 1003 participants (501 in the intervention group vs 502 control group). The detailed sample size calculations, assumptions and eligibility for study sites were published in the main trial protocol.[9]

Study variables

The study captured key variables known to influence outcomes of TBI in accordance with the National Institute of Neurological Disorders and Stroke, and orthopaedic injuries, aligned with the global surgery agenda to enhance national surgical care plans.[14 15] These variables included history of head trauma, head CT findings, intraoperative details, definitive surgical treatment, demographic factors, comorbidities, commute distance, injury mechanisms, road user categories, helmet use, prehospital care and transport, referral intervals, multiplicity of injuries and injury severity, as assessed by the Glasgow Coma Scale (GCS) and Kampala Trauma Score (KTS).[16]

The outcome variables were all-cause 90-day mortality and morbidity related to TBI and musculoskeletal injuries. Mortality was defined as the death rate within the population. TBI morbidity was evaluated using the 5-point Glasgow Outcome Scale (GOS), while musculoskeletal morbidity was measured through the Trauma Outcome Measure Score (TOMS) at 90 days, compared with the Trauma Expectation Factor Score (TEFS) at admission. These instruments gauge patients' recovery concerning pain, physical function, disability, satisfaction and overall quality of life.[17 18]

Statistical analysis

The clustered nature of the data predetermined our approach to data analysis. Since there were no differences in the demographic and clinical characteristics between treatment arms among participants lost to follow-up, a complete case analysis approach was employed, assuming that data were completely missing at random. To explicitly account for within-cluster similarities and between-cluster heterogeneity, and to account for intervention effects, multi-level conditional mixed effects regression models were employed for data analysis. Descriptive statistics were employed to analyse participants' baseline characteristics. Following established methodologies, the GOS was categorised into unfavourable (scores 1–3) and favourable (scores 4–5) outcomes.[17] Musculoskeletal injury outcomes were similarly classified as unfavourable (TOMS <TEFS) and favourable (TOMS ≥TEFS).[18] Keeping other covariates and all clustering random effects constant, mixed-effects logistic regression models, specifically the "melogit" command, were used to identify factors related to 90-day mortality and unfavourable morbidity outcomes, while adjusting for confounding variables. This approach accounted for baseline variations, intervention effects and potential imbalances due to loss to follow-up, assuming that missing data were random. Time-to-event Cox regression models stratified by treatment allocation were applied to reduce the potential bias due to informative censoring.

The treatment allocation (intervention vs control) served as the unit of analysis. ORs, HRs and 95% CIs were reported as effect size estimates. The intra-cluster correlation coefficient

(ICC) was calculated using the 'estat icc' command in the mixed-effects restricted maximum likelihood (REML) regression model as the ratio of between-cluster outcome variance to total outcome variance between and within clusters.

Covariates were assessed for confounding and effect modification using Cochran-Mantel-Haenszel statistics. Statistically significant variables in bivariate analysis, but not in Mantel-Haenszel strata, were excluded from the multivariable model. Relevant random variables with $p<0.2$ and those with biological plausibility, such as KTS and GCS, were retained. Analyses were conducted in Stata 15.0 at a 95% CI, with significance at $p<0.05$.

Patient and public involvement

Trauma care frontliners were engaged during a 1-day consultative meeting to inform relevance of the research tools as described in the study protocol.[9]

Ethical consideration

The Uganda National Council for Science and Technology approved the study (Ref: SS 5082), and all participants or their legally authorised representatives gave written informed consent before enrolment.

RESULTS

The sociodemographic and clinical characteristics of study participants are detailed in the main trial report[19] and summarised in online supplemental appendix 1. Briefly, of the 1003 participants, 82% (n=817) were male and 18.5% (n=186) were female, with a median age of 28 years (IQR: 22–37 years) (intervention: 28 (22-38) vs control: 28 (22-36)). Musculoskeletal injuries were present in 79.7% (799/1003) (intervention: 79.8% vs control: 79.5%) whereas head trauma was present in 94.6% (949/1003) (intervention: 96.2% vs control: 93.0%). Only 25.3% (254/1003) used helmets (intervention: 22.8% vs control 27.9%), and symptomatic TBI was present in 69.7% (699/1003) (intervention: 69.3% vs control: 70.1%). The overall median KTS and GCS were 8 (IQR: 7–9) and 14 (IQR: 11–15) respectively, and did not differ between treatment arms (p=0·360; p=0·123).

Factors associated with 90-day all-cause mortality

Bivariate analyses of factors associated with 90-day all-cause mortality are presented in section 1 of (online supplemental appendix 2). Of the 1003 participants, 88.4% (n=887) had complete 90-day follow-up data, of whom 9.2% (n=82/887) died. The overall median survival time before death was 3 days, IQR (1-8) and did not differ between arms (p=0.484). At bivariate analyses, the variables associated with mortality included mode of arrival, multiplicity of injuries, injury severity based on KTS and GCS, head and brain CT diagnosis, and type of neurosurgical intervention.

Multivariable mixed-effects regression analysis, adjusting for confounding, and maintaining other covariates and random effects constant, identified statistically significant predictors of 90-day all-cause mortality as detailed in section 2 of (online supplemental appendix 2). These included referral to hospital dispatch interval >1 hour (OR 4.215, 95% CI (1.802 to 9.858)), KTS ≤6 (OR 7.696, 95% CI (1.932 to 30.653)), GCS 9–12 (OR 3.432, 95% CI (1.194 to 9.870)) and GCS≤8 (OR 6.919, 95% CI (2.212 to 21.645)). Compared with participants with negative CT scans, the highest odds of mortality were among those with intra-axial lesions (OR 78.647, 95% CI (9.871 to 626.587)), followed by extra-axial lesions (OR 11.933, 95% CI (1.386 to 102.750)) and skull fractures (OR 11.366, 95% CI (1.197 to 107.977)). Conversely, craniotomy was associated with lower odds of 90-day mortality (OR 0.260, 95% CI (0.0954–0.706))]. Analyses of time-to-event (death) using stratified cox regression models revealed that the HR was significantly lower for participants who underwent emergency craniotomy [HR 0.346, 95% CI (0.165 to 0.727), p=0.005] (online supplemental appendix 3).

Factors associated with morbidity of neurological injuries

Section 3 of online supplemental appendix 2 summarises the bivariate analysis of factors associated with unfavourable Glasgow Outcome Scale (GOS) scores. The median GOS was 5 (IQR: 4–5) and the proportion of participants with unfavourable GOS (scores 1–3) was 14.5% (129/887). Statistically significant factors associated with unfavourable GOS included age, marital status, mode of prehospital transportation, prehospital interval, number of injuries, injury severity based on KTS and GCS, head and brain CT findings, neurosurgical treatment and presence of comorbidities.

Holding random effects and other covariates constant, multivariable mixed-effects regression analysis, adjusting for confounding, identified five key factors associated with unfavourable GOS scores. These included increasing age (OR 1.029, 95% CI (1.013 to 1.045)), sustaining more than one injury (OR 4.559, 95% CI (1.185 to 17.531)), KTS 7–8 (OR 2.755, 95% CI (1.285 to 5.906)), KTS ≤6 (OR 7.551, 95% CI (2.815 to 20.255)), GCS 9–12 (OR 4.071, 95% CI (1.901 to 8.719)) and GCS ≤8 (OR 13.779, 95% CI (5.643 to 33.645)). Conversely, craniotomy was associated with reduced odds of unfavourable GOS (OR 0.490, 95% CI (0.075–0.295)) (See section 4 of online supplemental appendix 2).

Factors associated with morbidity of musculoskeletal injuries

Among the 637 of 799 (79.7%) patients with musculoskeletal injuries who had complete Trauma Expectations Factor (TEFS) and Trauma Outcome Measure (TOMS) scores at 90 days, the majority (75.0%, 478/637) had a favourable outcome, with trauma outcome scores equal to or exceeding their trauma expectation scores. As shown in section 5 of (online supplemental appendix 2), factors associated with unfavourable TOMS scores in the bivariate analysis included: increasing age, being married and presence of comorbidities.

Multivariable mixed-effects logistic regression analysis of factors associated with unfavourable patient-reported outcome measures (PROMs) for musculoskeletal injuries is summarised in section 6 of (online supplemental appendix 2). Keeping other covariates and random effects constant, the results indicate that being married (OR 1.984, 95% CI (1.322 to 2.976)), sustaining multiple injuries (OR 1.762, 95% CI (1.001 to 3.100)) and being enrolled after the onset of the COVID-19 pandemic (OR 2.095, 95% CI (1.199 to 3.659)) were associated with higher odds of unfavourable PROM scores.

DISCUSSION

This study investigated factors associated with all-cause mortality and patient-related morbidity from motorcycle crash injuries. It revealed that patients referred from level III to level I trauma centres who experienced a delay of over 1 hour between the referral decision and dispatch were four times more likely to die than those transferred within 1 hour. This finding aligns with a Ugandan study indicating increased mortality for neurosurgical

referrals arriving more than 4 hours post-injury,[20] showing that delayed referral execution is a crucial factor in these delays.

Consistent with a Dutch study of 22 525 injured patients,[21] no significant association was observed between prehospital transportation time exceeding 1 hour and mortality. This is attributed to the inadequate capacity of our public and ambulance transport systems to provide sufficient prehospital care. In contrast, timely referral decision-making significantly affected outcomes, highlighting the importance of careful planning regarding necessary imaging, lab tests and specialised surgical resources. Previous systematic reviews have shown that for haemodynamically unstable injuries, the injury-intervention interval impacts mortality; however, quality prehospital care is more beneficial than expedited transport for stable patients.[22] This study enhances understanding of the impact of prehospital time on mortality in LMICs, given most existing literature emerged from HICs.[22]

Helmet utilisation among study participants was only 25%, insufficient to establish a significant correlation with mortality and GOS outcomes. Besides, helmet utilisation alone masks unmeasured confounders such as crash worthiness quality, appropriate anatomical fitting and mass effect which were beyond the scope of this study. While this usage rate is an improvement from the previous 19%[1] and over the 20% documented in Kenya, it remains below the global average.[4]

Injury severity, assessed via the KTS, showed a near eightfold mortality increase at 90 days for scores of ≤6. GCS scores of 9–12 and ≤8 were associated with more than threefold and sevenfold increases in mortality, respectively. These findings corroborate the TRACK-TBI[23] and America's National Trauma Data Bank studies,[24] demonstrating the predictive ability of KTS[25] and GCS[26] for mortality in multiply injured and traumatic brain injury (TBI) patients. Increased mortality among individuals with a GCS of 9–12 in our settings may result from delays in seeking, reaching and receiving definitive TBI care,[20 27] influenced by factors such as caretaker literacy, fragmented health systems, limited insurance coverage and resource allocation dynamics in healthcare settings.[11] To enhance access to neurosurgical care in LMICs, the study recommends formalising the emergency prehospital care system through specialised trauma training including for paramedics, improving infrastructure for neurocritical care, streamlining referral protocols from lower to higher trauma centres and between public and private hospitals and addressing healthcare financing with inclusive insurance coverage. The MOTOR trial and RTTDC interventions sought to mitigate delays in receiving definitive care, potentially reducing adverse outcomes due to delayed treatment of primary life-threatening injuries related to musculoskeletal and neurotrauma.

In addition to mortality, participants with KTS scores of 7–8 exhibited a threefold increase in the likelihood of poor GOS outcomes, escalating to 7.5 times for scores ≤6. Additionally, GCS scores of 9–12 correlated with fourfold higher odds of unfavourable GOS outcomes at 90 days and a 13-fold increase for scores ≤8. These results are congruent with the USA TRACK-TBI[23] and European CENTER-TBI[28] studies. Although the GCS is generally found to be superior to KTS in predicting TBI outcomes,[29] this research emphasises the need to contextualise trauma scores alongside clinical evaluations, biomarkers, imaging and psychosocial-environmental modifiers.

Age and the multiplicity of injuries were identified as modifiers of functional outcomes. Evidence from Norway suggests that younger individuals have more favourable outcomes while older patients experience worse prognoses.[30] Furthermore, the presence of multiple acute injuries was associated with a 4.5-fold increase in the likelihood of poor GOS. This is supported by emerging evidence suggesting that TBI may enhance healing in extra-cranial injuries such as fractures[31] but can also increase disability risk due to surgical and anaesthetic stresses.[32] These findings underscore documenting extra-cranial injuries as essential for risk stratification to enhance trauma triage and registry protocols.

The study indicated that skull fractures significantly raised the risk of 90-day mortality to 11-fold, with risks escalating to 12-fold in the presence of extra-axial lesions such as acute epidural, subdural or subarachnoid haemorrhages, and increased dramatically to 78 times if axial lesions such as contusions, intraventricular haemorrhage or traumatic axonal injury were detected. The findings reinforce the hypothesis that extra-axial lesions are associated with better mortality outcomes compared with axial lesions, which present greater surgical challenges.[33] However, in terms of morbidity, this classification failed to predict functional outcomes, as most patients with extra-axial lesions, including diffuse axonal injuries, ultimately succumbed to death in our resource-limited environment.

Although craniotomy showed a substantial reduction in both mortality (74.0%) and unfavourable outcomes (85.1%) compared with decompressive craniectomy (41.5%; 20.6%), the benefits of each surgical approach depend on the context of injury severity. Moreover, the results can also be interpreted so that decompressive craniectomy was performed in patients who had more severe and diffuse parenchymal intracranial injuries on head CT compared with patients treated with craniotomy for focal lesions, which may explain part of the difference. Our results conform to existing literature on the relative occurrence of intracranial haematomas, application and benefits of the respective surgical approaches.[11 34] Although the optimal surgical management of intracranial haemorrhage to achieve decompressive efficacy has been contentious over the past decade with variable practice,[35] historical data from systematic reviews and meta-analyses supports craniotomy as generally leading to better outcomes,[36 37] including lowering risk of post-operative infections which may offer survival advantage and reducing reoperation rates which is critical for saving costs in low-resource settings.[37] Until larger quality validation randomised control trials are available, there is a need for patient-centric surgical decision-making tailored to individual injury profiles, but identifying the ideal patient profile who would benefit the most from decompressive craniectomy should be the subject of future research.

Post-adjustment, factors linked to unfavourable outcomes in musculoskeletal injuries included multiple injuries, marital status and sustaining injuries during the post-COVID-19 pandemic. Psychosocial dynamics, including relationship quality and support systems, were highlighted, with married status correlating with poorer outcomes. Marital relationships can enhance quality of life after trauma through emotional support, but they may also introduce stressors due to financial obligations in African contexts with dependent families. Social dependency has been associated with unstable relationships following trauma in systematic reviews and Danish studies.[38 39] In this study, spouses' involvement in care decisions and the socioeconomic impact of COVID-19 influenced participants' perceptions of recovery, particularly concerning their ability to return to work for family support. Future research should quantify this relationship by examining quality of life from the perspectives of married partners both with and without injuries. These findings highlight the necessity for patient-centred, injury-specific

rehabilitation approaches, as definitions of successful recovery vary across cultural and familial landscapes. Thus, psychosocial patient-reported outcomes should be included as indicators when evaluating functional musculoskeletal and neurotrauma care systems to better assess return to pre-injury status.

Study limitations

The study acknowledges several limitations. First, the challenges posed by a smaller sample size for rare injuries led to wide CIs, increasing the degree of uncertainty of the effect size estimates. Moreover, aggregating TBI and dichotomising trauma outcomes could have resulted in loss of information. The use of rare events prediction models and neural networks with machine learning algorithms is an emerging approach to addressing this challenge since variance weighted cluster-level mixed effects regression models did not adequately address this issue. Second, the short duration of follow-up could have missed some functional improvements undetectable by GOS scale until 6–12 months post-injury. Third, there are limitations in generalisability due to focusing the study on motorcycle-related injuries, excluding penetrating TBI which present distinct outcome characteristics. Finally, a lack of MRI and blood-based biomarkers data in our resource-limited set-up and having 11.6% missing data on morbidity outcome variables constrains prognostic information, in addition to the potential for interobserver variations during data acquisition which could introduce bias. Despite these limitations, this research represents one of the largest inquiries into mortality and morbidity outcomes from motorcycle crash-related injuries in Uganda, providing essential insights for future research and healthcare practice. Moreover, our analyses were robust given the risk adjustment, and all experiments were reviewed and approved by authors of the parent trial.

CONCLUSIONS

The research findings indicate that five key factors were determinants of 90-day mortality and unfavourable outcome, including referral decision to dispatch interval, presence of axial and extra-axial lesions, skull fractures, multiplicity of injuries and injury severity based on the KTS and GCS. Conversely, craniotomy was identified as a protective factor. For patient-reported outcomes related to musculoskeletal injuries, the key determinants were multiplicity of injuries, marital status and sustaining injuries during the post-pandemic period. These critical factors should constitute core outcome sets for future prospective trials, trauma registries and predictive machine learning models that incorporate demographic, injury mechanism, clinical and CT imaging data. Additionally, long-term trials should evaluate similar outcomes for diverse injury mechanisms such as motor vehicle crashes, falls and assaults.

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Contributors HL was the lead researcher who conceived, designed and implemented the study and wrote the initial draft of the manuscript. RS, PK, AK, BO and HMML assisted with administrative tasks, data acquisition and participant follow-up and provided critical review of the manuscript. HL, MM and AA were responsible for data analysis and cross-validation. TB critiqued the study methods. Funding for the project was obtained by JPP, MLW, TB and HL. MLW and JPP supervised the study and provided critical review of the final manuscript. HL is the overall guarantor. All authors read and approved the final version of the manuscript. Microsoft Copilot was used to refine grammatical errors.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Ethical approval for this research involving human participants was granted by the Research and Ethics Committees of Mbarara University of Science and Technology (Ref: 1/7; 05/5-9) and the Uganda National Council for Science and Technology (Ref: SS 5082). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available in a public, open access repository. The anonymised data underlying the findings of this ancillary study are available within this article as (online supplemental appendixs 1–3). Additionally, the dataset and analysis code pertaining to both the ancillary study and the parent trial, which is registered with the Pan African Clinical Trial Registry (PACTR202308851460352), are publicly accessible at https://data.mendeley.com/datasets/bgpmkpcwdt/1.

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