Community Intervention for Tuberculosis Contact Tracing and Preventive Treatment - a cluster randomized study (CONTACT)

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CONFLICT OF INTEREST DISCLOSURE FORM

☑ I have no Conflict of Interest to report.

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STUDY RATIONALE

- Poor implementation of TB preventive treatment (TPT) among child contacts
  - Difficulty to exclude TB disease in children
  - Operational constraints
  - Poor adherence of the 6 months isoniazid preventive therapy
  - **Parents hesitant to bring healthy children to facility for screening and TPT management**

- **Hypothesis: A community-based approach could increase the proportion of child contacts who initiate and complete TPT**
  WHO pragmatic approach
  - Symptomatic screening enough to exclude active TB in child contacts < 5 years or 5-14 years HIV positive (high priority group)
  - No need to confirm MTB infection

STUDY OBJECTIVES

- **Primary objective**
  To compare the proportion of household child TB contacts eligible for TPT (<5 years and HIV-infected children 5-14 years) who initiate and complete TPT using a community-based approach vs the standard of care for contact screening and TPT management

- **Secondary objectives**
  To compare the community-based approach and the standard of care in terms of:
  - Cascade of care for the initiation and completion of TPT
  - Cascade of care for TB detection
  - Acceptability by parents/guardians, health personnel and community
  - TPT safety
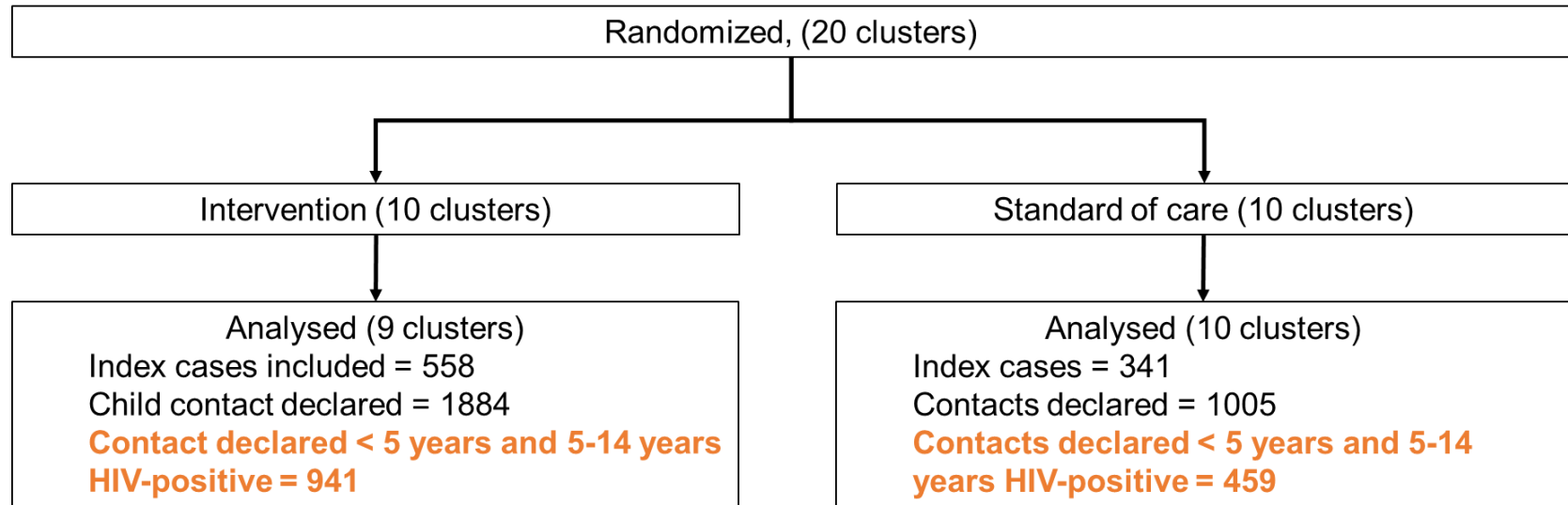 - Cost and cost-effectiveness of the different approaches

METHODS

- **Design:** Pragmatic cluster randomised trial comparing
  - **Standard of care :** Facility-based for symptom screening, TPT (3 rifampicin-isoniazid) initiation and follow-up
  - **Intervention:** Community-based for symptom screening, TPT (3RH) initiation, and follow-up

- **Setting:** 20 clusters in Cameroon and Uganda
  CaP-TB supported facilities with TB diagnosis and catchment area

- **Sample size for primary endpoint:** 1500 declared child contacts < 5 years or 5-14 years HIV+

- **Acceptability**
  - 12 focus group discussion with TB patients divided by gender
  - 24 in-depth interviews with healthcare providers and community leaders

- **Implementation of the intervention** : Oct 19 – Aug 22
  Put on hold due to COVID: April – Sept 20 in both countries and Jun- Aug 21 in Uganda

1. Vasiliu et al 2021. Trials

STUDY INTERVENTION
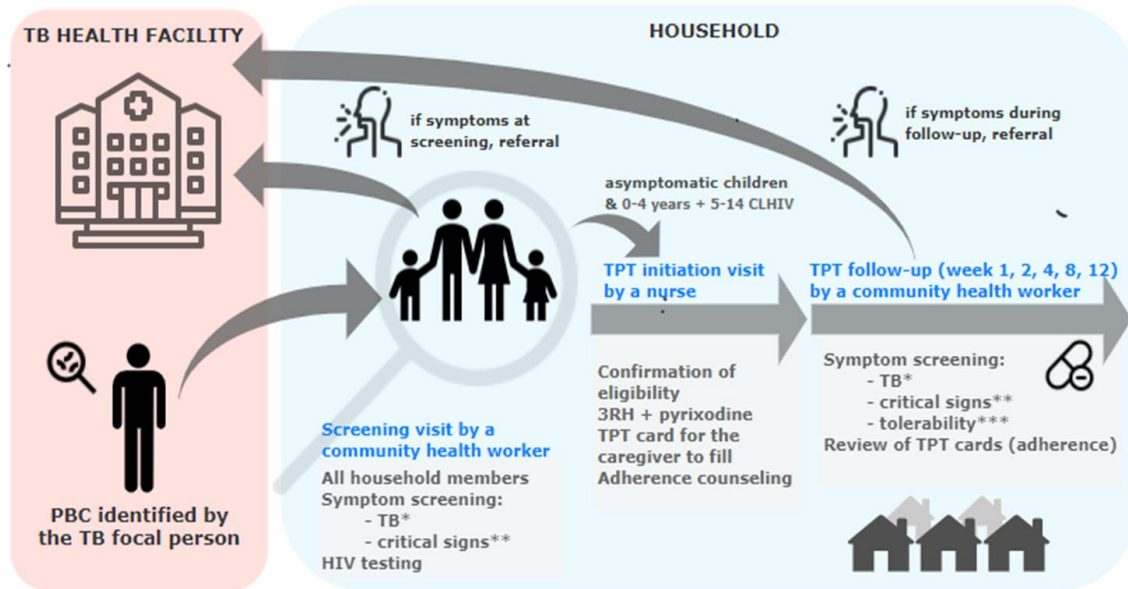
Household child contact = child <15years who shared the same living space as the index case for one or more nights or for frequent (more than 3 days per week) or extended (half day or more) daytime periods during the 3 months before the start of treatment.

RESULTS: FLOW DIAGRAM

Randomized, (20 clusters)

Intervention (10 clusters)

Standard of care (10 clusters)

Analysed (9 clusters)
Index cases included = 558
Child contact declared = 1884
Contact declared < 5 years and 5-14 years HIV-positive = 941

Analysed (10 clusters)
Index cases = 341
Contacts declared = 1005
Contacts declared < 5 years and 5-14 years HIV-positive = 459

INDEX AND DECLARED CHILD CONTACTS' CHARACTERISTICS

Variable, median (IQR), n (%)	Intervention	Standard Of Care
Index cases	N = 558	N=341
Age (years)	38.4 (29, 49)	36.5 (29, 49)
Female	207 (37.1)	119 (34.9)
HIV positive	139 (24.9)	72 (21.1)
Child contacts	N=1884	N=1005
< 5 years	938 (49.8)	458 (45.6)
Female	946 (50.2)	500 (49.7)
Relation to index case		
Daughter/son/sibling	780 (41.4)	501 (49.8)
Other family member	1058 (56.2)	501 (49.8)
Not family	46 (2.4)	3 (0.3)

PRIMARY ENDPOINT ANALYSIS

Proportion of declared child contacts (< 5 years or 5-14 years HIV+) who initiate and complete the TB preventive treatment
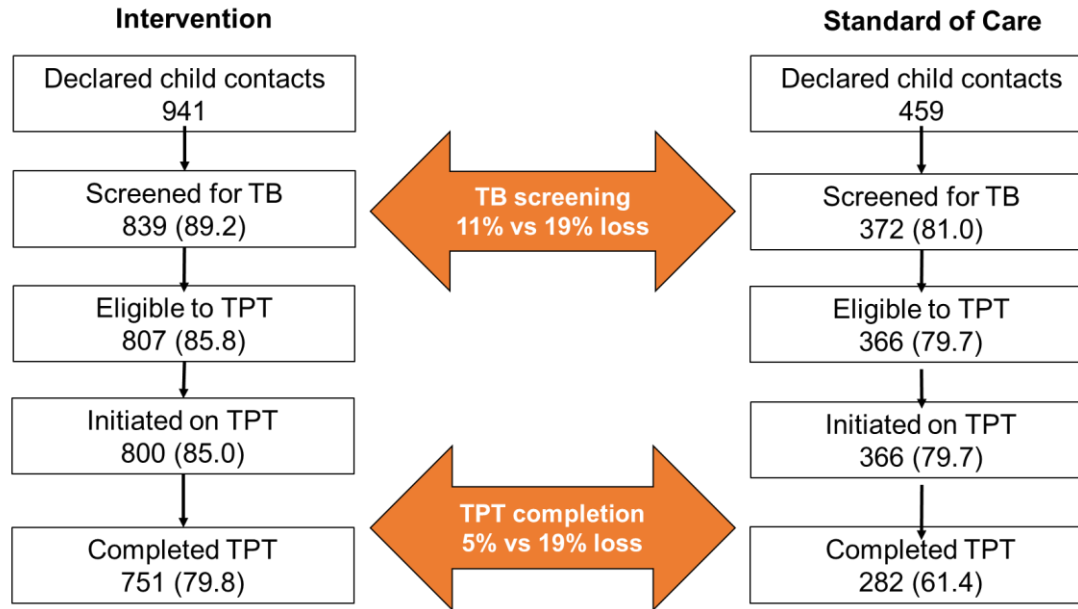
Intervention	Standard of Care	Individual level*		Cluster level	
n/N, %	n/N, %	OR [95% CI]	p	RR [95% CI]	p
751/941 (79.8)	**282/459 (61.4)**	3.03 [1.23;7.44]	0.019	1.27 [1.01;1.49]	0.040

* logistic mixed model with a logit link function using fixed effects of model assignation, country and number of index cases per cluster and one random-effect for the cluster; correction for small number of clusters using degree-of-freedom Between-Within method
Intra cluster correlation: 0.096
OD: odds ratio, RR: relative risk

# TPT MANAGEMENT CASCADE OF CARES

TB DETECTION CASCADE OF CARES (ALL CHILD CONTACTS)

	Intervention	Standard of care
Declared child contacts	1884	1005
Screened for TB	1550 (82.3)	474 (47.2)*
TB suggestive, n (%)	102 (6.6)	35 (7.4)
Investigated for TB, n(%)	82 (80.4)	35 (100)
TB diagnosis, n(%)	8 (9.9)	1 (2.9)
TB treatment started, n(%)	7**	1

* Standard of Care focused on < 5 years old child contacts
**TB treatment refused by the parent

ACCEPTABILITY BY BENEFICIARIES AND HEALTH CARE PROVIDERS
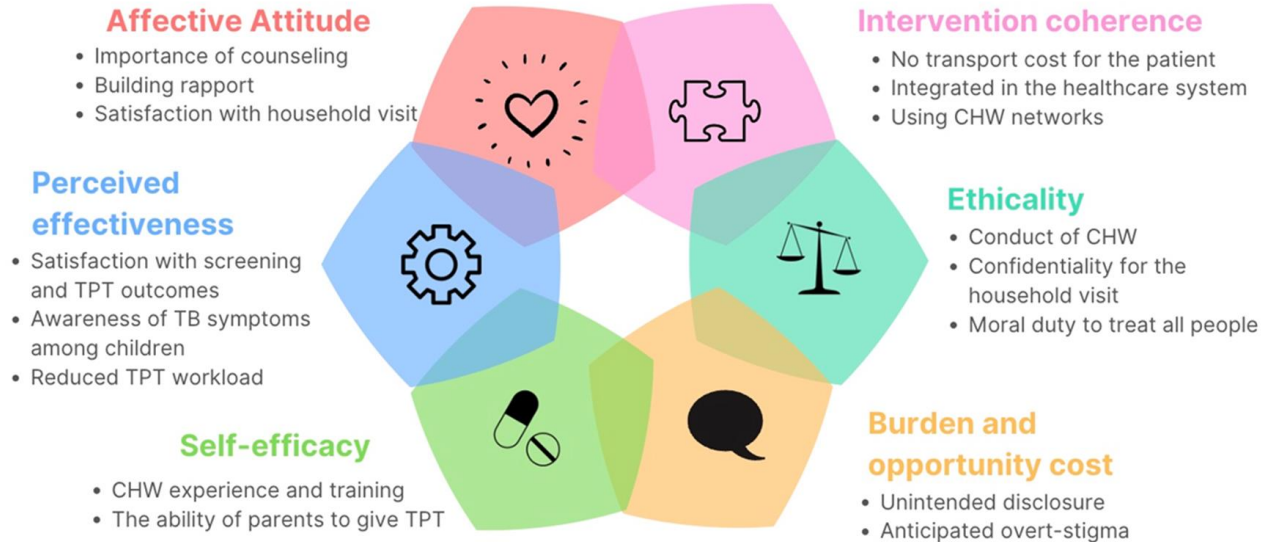
E-Poster No. EP-04-636. Acceptability and feasibility of household child-contact investigation and preventive treatment management in Cameroon and Uganda: a qualitative assessment

CONDITIONS FOR THE TPT COMMUNITY-BASED APPROACH

- CHW
  - o Selection: experience and motivation
  - o Existing network: integration with other tasks (TB and other diseases), workload to be monitored
  - o Training and good code of conduct
  - o Secure transport and communication cost for CHW: incentives. Issue with sustainability.

- Adapted tools
  - o Job aids: TB symptoms, tolerability assessment, indication of immediate referral
  - o TPT adherence tools

- Mentoring and supervision by TB focal person requiring a good communication

- Drugs
  - o Dispensation and storage at health facility by TB focal person
  - o No dose adaptation during f-up: issues with carrying scale

- Importance of counselling
  - o Initial counselling of index case by TB focal person
  - o Trusting environment: respect of confidentiality

CONCLUSION

- Significant increase of child contacts who initiated and completed TPT with the community-based intervention: +20%

- Increased number of contacts (children and adults) screened and diagnosed with TB with the community-based model

- Community-based intervention feasible and acceptable by beneficiaries and health care providers

- Additional benefits of the community based approach

  - Integration of TB and HIV screening at community level

  - Integrated cares for contacts and index cases

- Cost-effectiveness analysis in health facility and patients' perspective ongoing

ACKNOWLEDGEMENTS

- Participants: Index cases, contacts, child's parents/guardians
- Country research teams
  - Cameroon: Boris Tchounga, Boris Tchakounte, Collette Sih, Rogacien Kana, Patrice Tchendjou, Eric Youm, research assistants, TB focal persons, safety monitors and CHWs
  - Uganda: Daniel Atwine, Bob Ssekyanzi, David Otai, Rinah Arinaitwe, research assistants, TB focal persons, safety monitors and CHWs
- IRD: Anca Vasiliu, Elisabete de Carvalho, Savine Chauvet, Sayouba Ouedraogo, Benjamin Cuer
- EGPAF : Martina Casenghi, Mikhael DeSouza, Jennifer Cohn, Appolinaire Tiam, Maria Oziemkowska, Richard Okello, Henry Ijjo, Léonie Simo
- NTP: Stavia Turyahabwe (Uganda), Albert Kuate Kuate (Cameroon)
- Scientific Advisory Committee