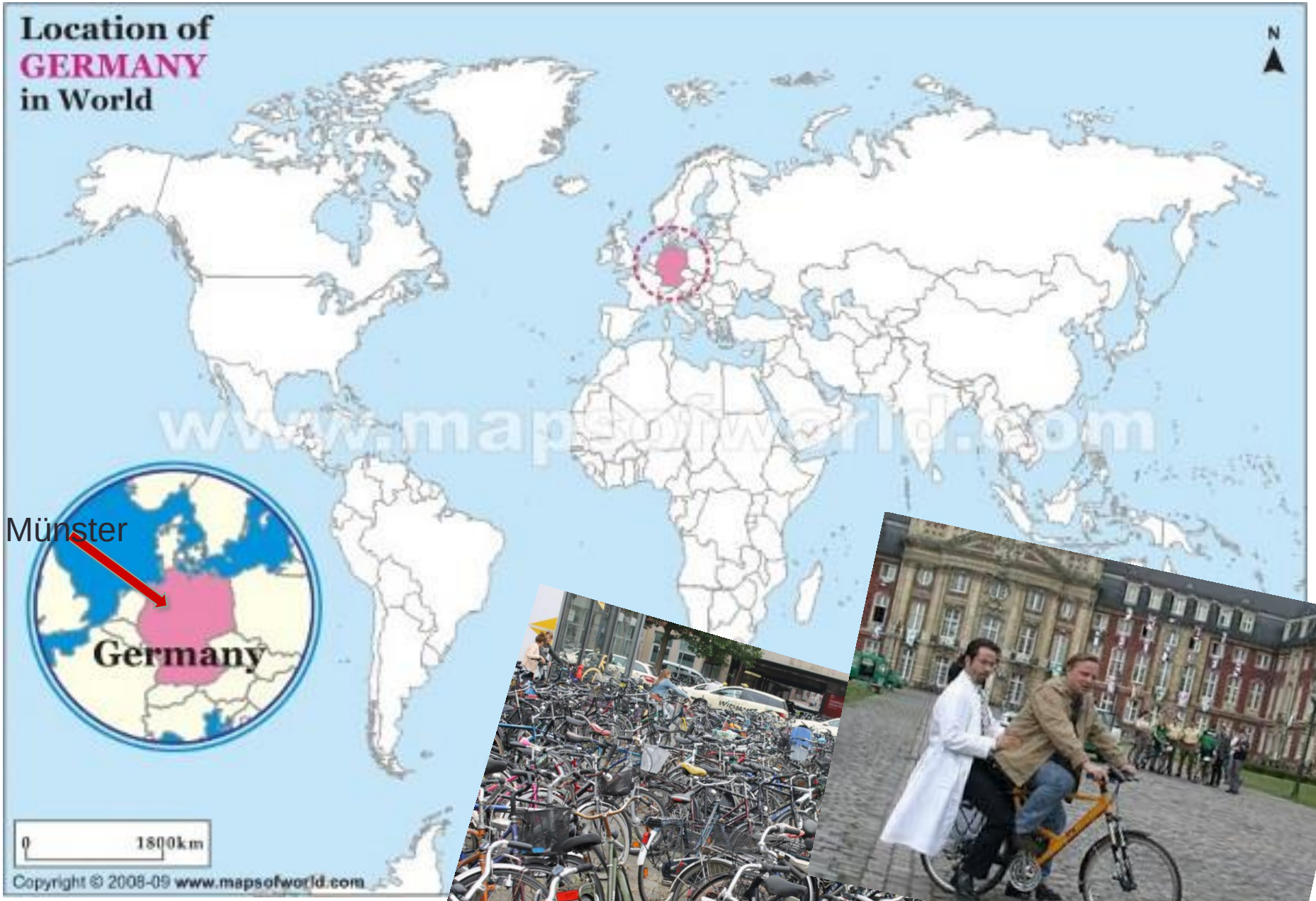
“Effects of an *HIV-Care-Program* on the health- Status of HIV- positive patients in jaoundé, Cameroon“: a cluster- randomized trial

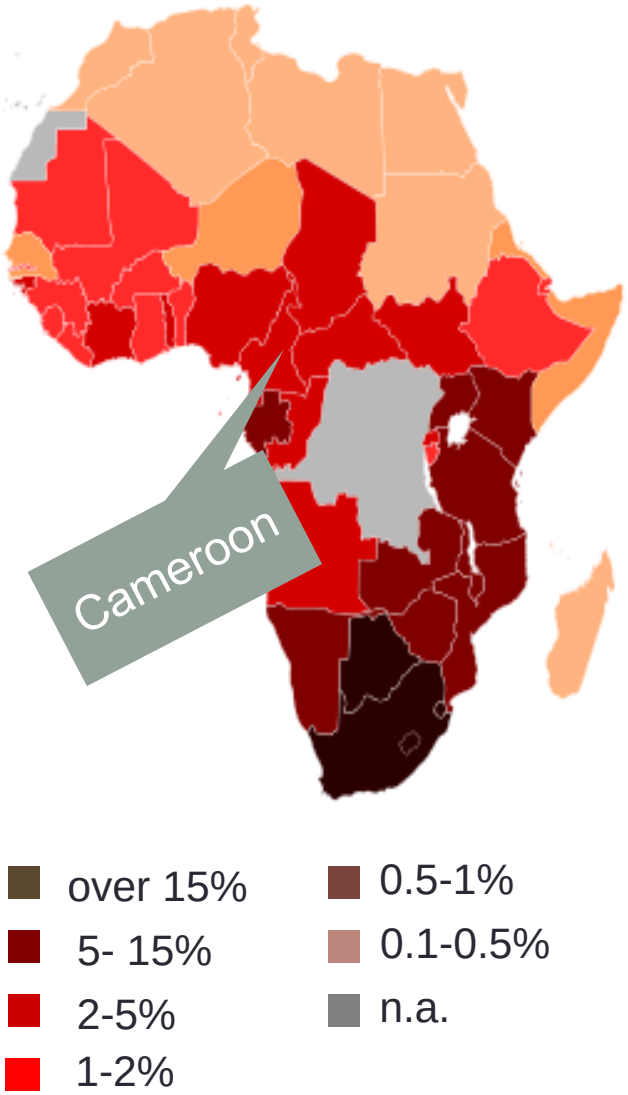
Indo- Global Summit & Expo on Health, New Delhi, October 6th 2015

Prof. Dr. Heike Englert, MPH
University of Applied Sciences, Muenster, Germany


Location of
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Background

- HIV-Prevalence
  - worldwide: approx. 39,5 Mio
  - in Cameroon: approx. 860.000
- Health Care:
  - since 2007:
    Antiretroviral Medication (ARV)
    for free (regulated by law)
  - de facto:
    only 76.000 are provided with ARV

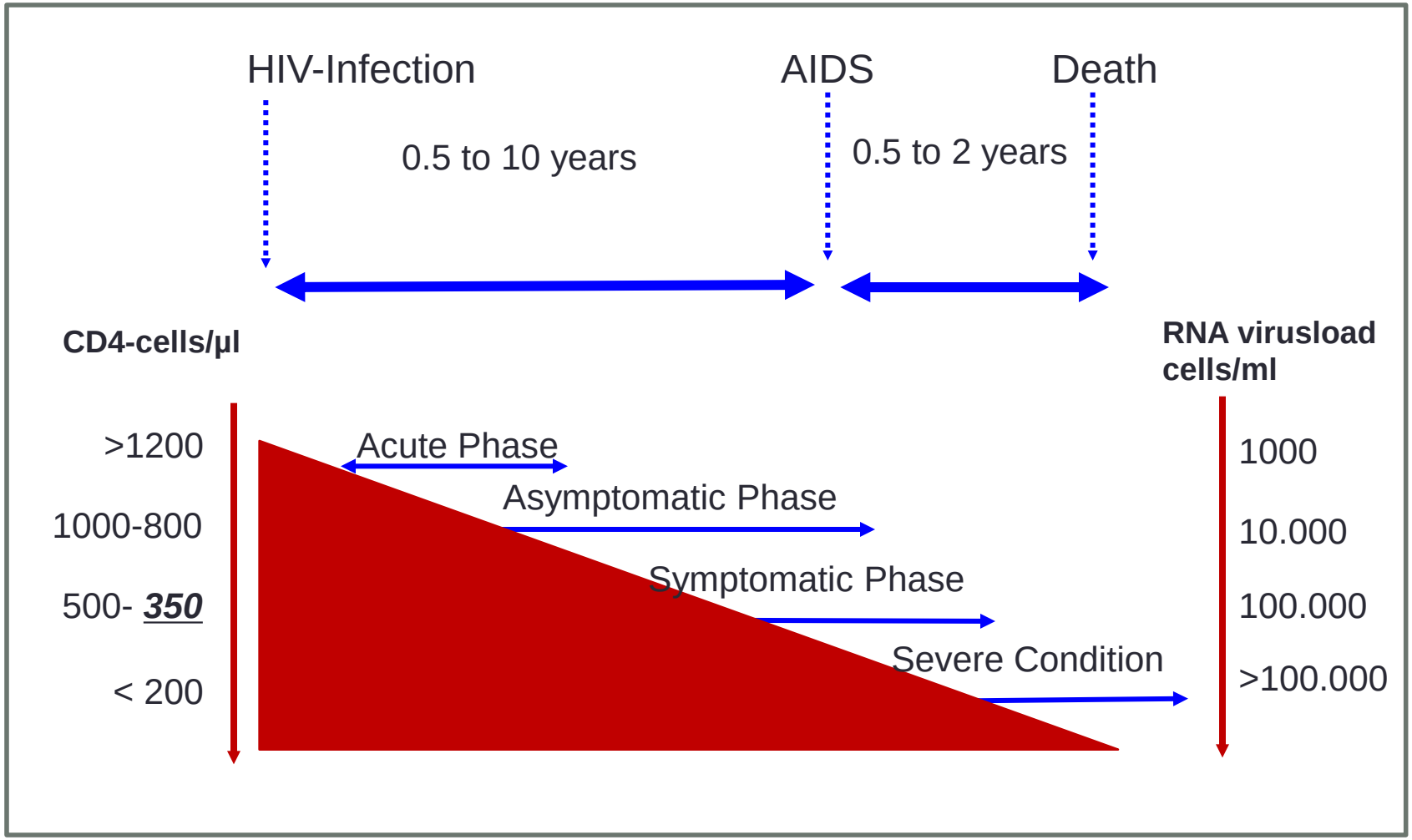


UNAIDS, 2011

World Development Indicators, Sept. 2014

Background

Progression of the HIV Infection in Adults



Chandrasekhar and Gupta 2011

Objectives

“Can the HIV-Care-Programm (HCP) focusing on nutrition, physical activity, hygiene and social support, extend the medication-free period and improve the clinical and anthropometric parameters in HIV-positive patients”?

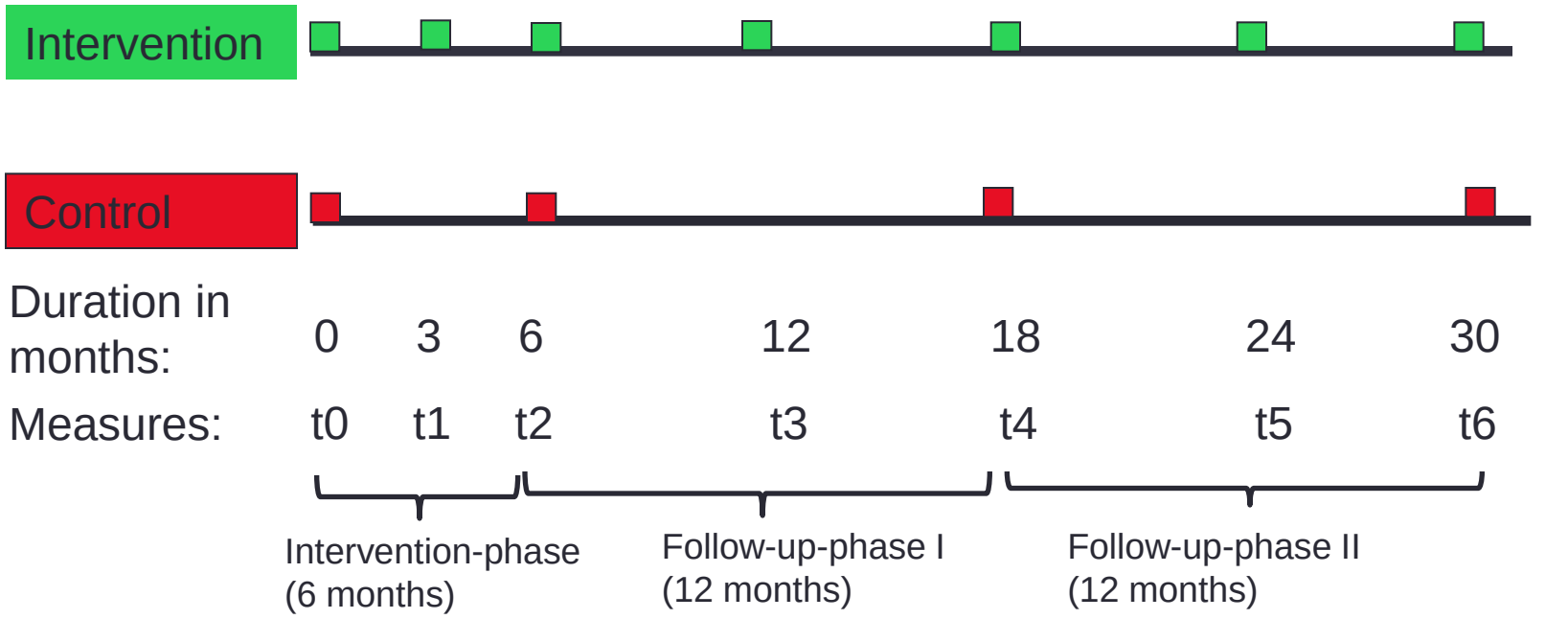
Aims

- Primary hypothesis:
  - “The HCP increases the **CD4-cellcount** in HIV-positive patients by 10% compared to the control group over a period of 6 months”.
  - “The HCP extends the **medication-free period** in HIV-positive patients by 10% compared to the control group over a period of 6 months”.
- Further examinations on:
  - **BMI**
  - **serum-albumin-level**
  - **plasma-malondialdehyde-level**
  - **eating behavior** (here: consumption of fruits- and vegetables)

Methods

- Cluster-randomized intervention study
- Inclusion criteria for hospitals (cluster):
  - treatment of HIV/AIDS patients
  - at least 100 registered HIV/AIDS patients
- Inclusion criteria for patients:
  - HIV-positive men and women between 20 and 72 years of age
  - CD4-cellcount >350 cells/µl
  - RNA virusload < 100.000 cells/ml
  - no ARV-therapy
  - available income for food: 1€/day
  - signed informed consent

Flow - chart



Intervention group:
Clinical parameters: CD4-cells, serum-albumin, plasma-malondialdehyde
Anthropometric parameters: BMI
Questionnaires: diet (FFQ, 3-day protocol), physical activity, hygiene, social support

Control group:
Clinical parameters: CD4-cells, serum-albumin, plasma-malondialdehyde
Anthropometric parameters: BMI
Questionnaires: diet (FFQ, 3-day protocol), physical activity, hygiene, social support

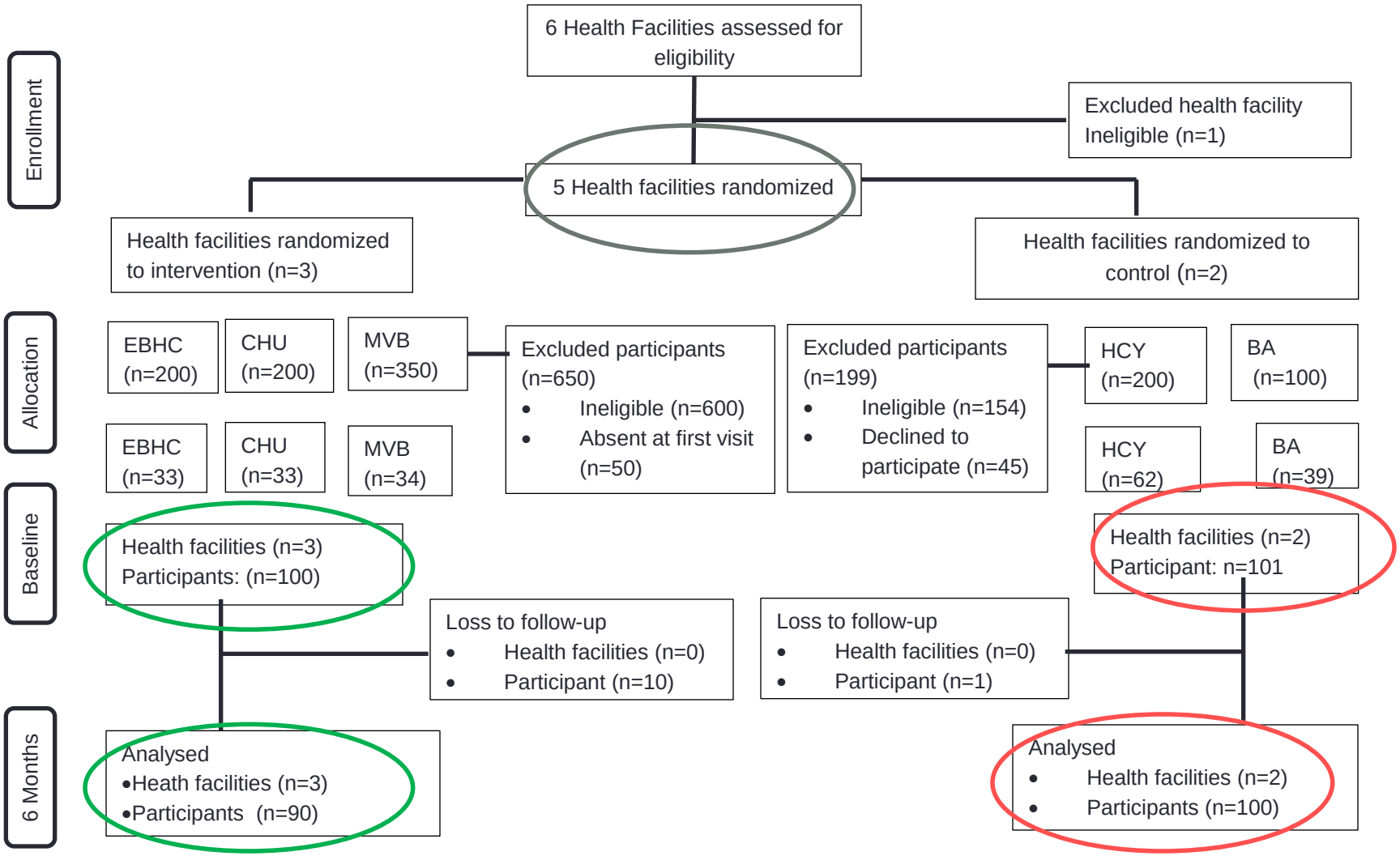
Intervention





- Initial, individual counseling
- Weekly group sessions (topics: diet, hygiene, physical activity and social support)
- Workshops and trainings („group-support“)
- „Train the Trainer“
- Control group: treatment „usual care“

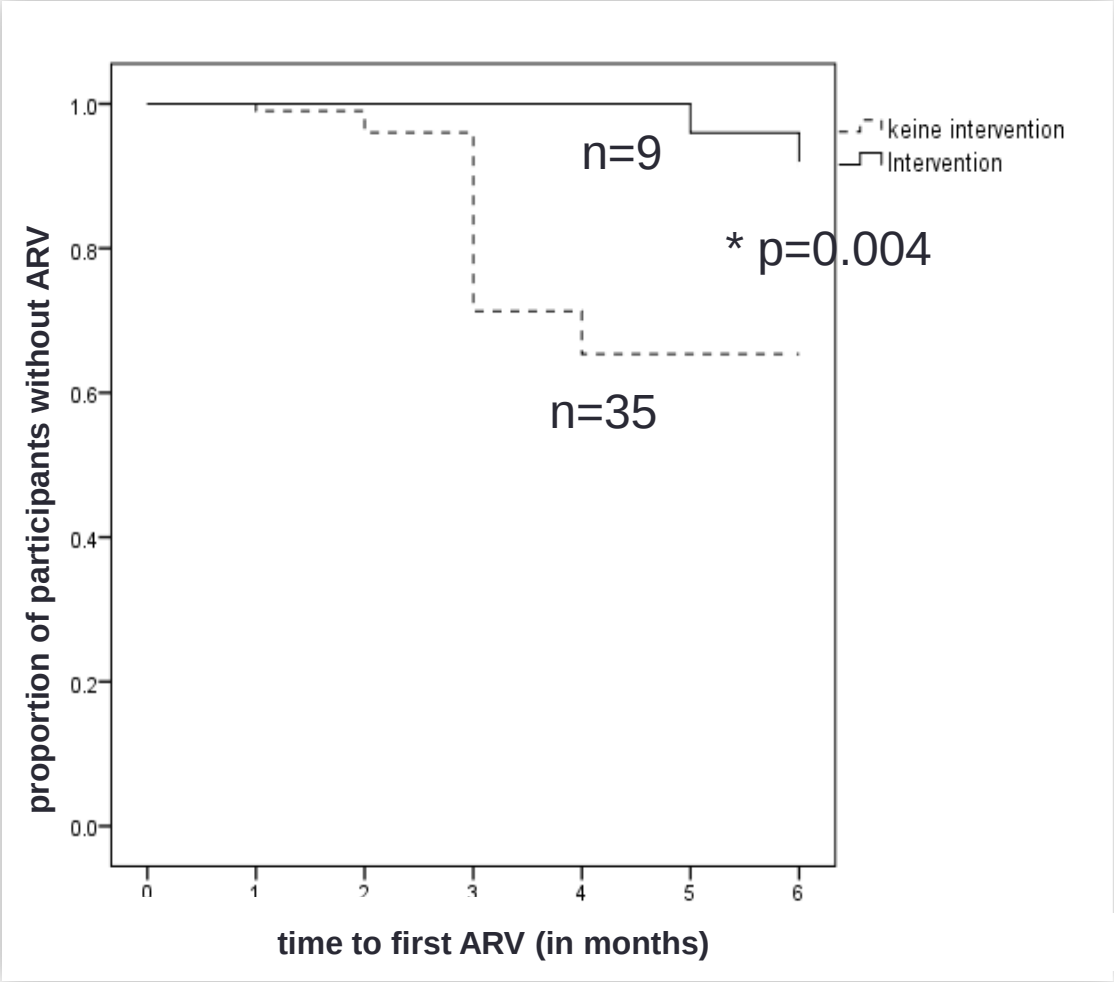
Study Recruitment



Etoug-ebe Baptist Health Centre (EBH), Mvog-besi Hospital (MVB), University Teaching Hospital (CHU), Yaoundé Central Hospital (HCY),Biyem-Assi Hospital (BA)

Results (1)

Medication-free period



* Logistic Regression with clusteradjustment ; Nkengfack et al. 2014 (International Journal of Public Health)

Results (2)

Trends of various outcome parameters

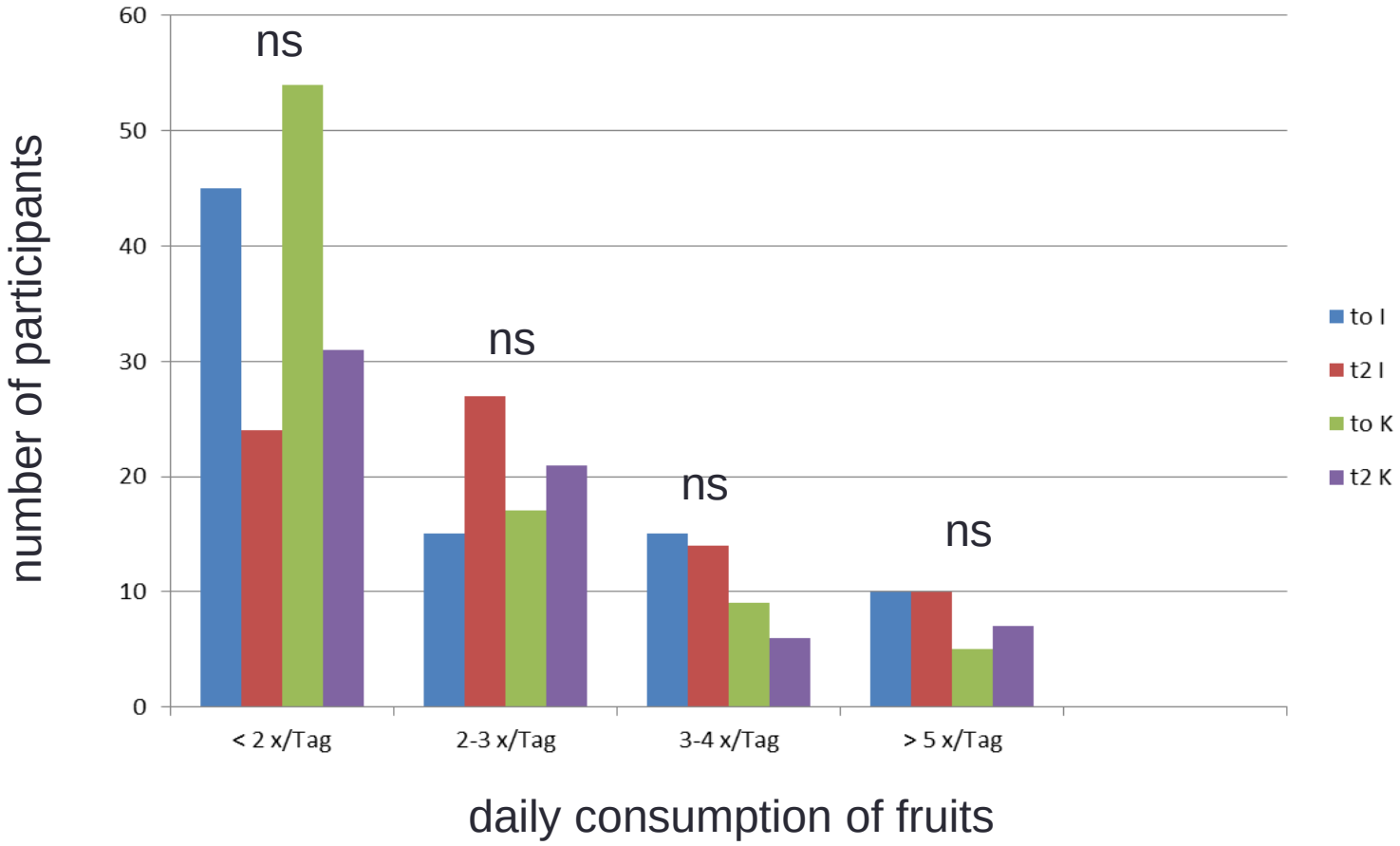
Parameter	Intervention group		Control group		
Measures (n)	Baseline (n=100)	After 6 months (n=90)	Baseline (n=101)	After 6 months (n=100)	p-value †
CD4 (cells/µl)*	603.6 (CI: 533.6, 673.6)	557.3 (CI: 477.9, 636.8)	561.4 (CI: 503.4, 619.5)	432.4 (CI: 370.6, 494.3)	0.003
BMI (kg/m²)*	26.1 (CI: 24.5, 27.6)	26.6 (CI: 24.9, 29.0)	25.8 (CI: 24.5, 27.1)	25.1 (CI: 23.7, 26.4)	0.088
Albumin (g/dl)* ǂ	2.1 (CI: 1.8, 2.4)	4.2 (CI: 3.8, 4.5)	3.4 (CI: 3.2, 3.7)	3.3 (CI: 3.0, 3.6)	<0.001
Malondialdehyde (µmol/l)*	3.3 (CI: 2.5, 4.0)	3.6 (CI: 3.1, 4.0)	3.4 (CI: 2.8, 4.0)	3.7 (CI: 2.3, 5.2)	0.934

* mean and Confidence interval (CI); ǂ Logtransformation at baseline; † ANCOVA with clusteradjustment

Nkengfack et al. 2013 (*Glob Epidemi Obes*), Nkengfack et al. 2014 (*International Journal of Public Health*)

Results (3)

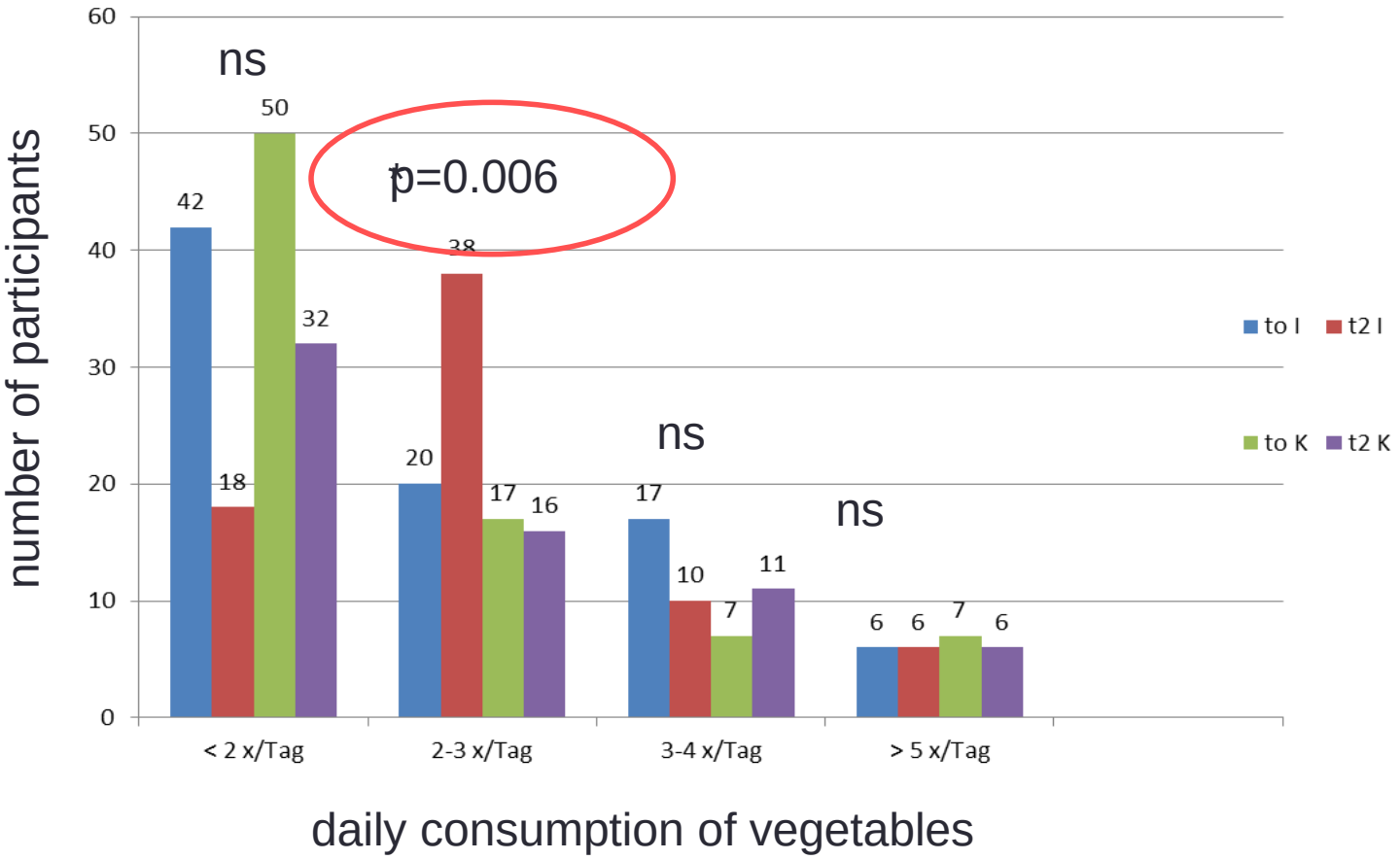
Eating behavior (daily consumption of fruits)



t0 = Baseline, t2 = after 6 months, I=Intervention group, C= Control group
** see publication: Nkengfack et al. 2013 (Oxid Antioxid Med Sci)

Results (4)

Eating behavior (daily consumption of vegetables)



t0 = Baseline, t2 = after 6 months, I=Intervention group, K = Control group

** see publication: Nkengfack et al. 2013 (Oxid Antioxid Med Sci)

Discussion

- Strength of the study
  - study design: RCT with cluster-randomization
  - duration of the study: 30 months
  - low “drop-out rate”
  - combination of qualitative and quantitative datacollection
  - representative data respective gender and age
  - although administrative barriers the study was conducted by GCP standards

Discussion

- Weakening of the study
  - calculated sample size of the study was failed
  - more measures in the intervention group
  - recommendations for fruit and vegetable consumption were not realized
  - subjective data collection of the eating behaviors (recall bias)
  - changes in HIV/AIDS patients:
    - general thinking: „wasting-syndrome“
    - our observations: overweight to hide the disease

Conclusions

- The results give significant hints for effectiveness of the *HIV-Care-Programm*
- To enhance the effect of HCP, compliance promoting procedures are necessary:
  - address the target groups more specific
  - offer more meetings and refresher courses
  - give incentives (e.g. provide healthy food)


Thank you for your attention!