Assessed for eligibility (n=2356)

Excluded (2%, n=47) history of hospitalization to allergic reaction
Not meeting inclusion criteria due to presence of caries (25% of 2309, n=577)
Refused to consent (30% of 1732, n=520)
Other reasons (1% of 1212, n=12)

Enrolment

Allocated to test group (n=600)
Received allocated intervention – preventive package fluoride varnish and fluoride toothpaste plus standardized health education (n=600)
Did not receive allocated intervention (n=0)

Allocated to control group (n=600)
Received allocated intervention – standardized health education only (n=600)
Did not receive allocated intervention (n=0)

Allocation

Lost to follow-up (14%, n=84)
Give reasons – Left practice, moved from area
Discontinued intervention (1%, n=6)
Give reasons – Dislike fluoride varnish intervention and concerns about effectiveness of intervention

Lost to follow-up (14%, n=84)
Give reasons – Left practice, moved from area
Discontinued intervention (1% n=6)
Give reasons – concerns about possible caries development

Follow-Up

Analyzed (n=510)
Excluded from analysis (n=0)
Give reasons – we will include all participants in the analysis

Analyzed (n=510)
Excluded from analysis (n=0)
Give reasons – we will include all participants in the analysis

Analysis