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# The effect of screen time on nighttime urinary incontinence

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 14/05/2022 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/05/2022 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 22/02/2023 | Urological and Genital Diseases | |

**Plain English summary of protocol**
Background and study aims
Bladder and nighttime bed wetting (nocturnal enuresis) are common problems in children. The aim of this study is to investigate if there is a relationship between screen time and the severity of primary monosymptomatic (meaning patients who have never been consistently dry at night) nocturnal enuresis (PMNE) and treatment success.

Who can participate?
Children and adolescents aged from 6 to 18 years

What does the study involve?
Patients with PMNE are randomly allocated to one of two groups and both groups are given treatment. One group is requested to reduce daily screen time to less than 60 minutes and the other group is given unrestricted screen time.

What are the possible benefits and risks of participating
Participants are expected to benefit from reduced screen time by progressing in various developmental stages, including emotional, cognitive, behavioral, and sleep quality.
There are no known risks to participants.

Where is the study run from?
Afyonkarahisar Health Sciences University Hospital

When is the study starting and how long is it expected to run for?
February 2021 to October 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Arif Demirbas
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# Contact information

### Type(s)
Principal Investigator


### Contact name
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
The effect of screen time on the presentation and treatment of primary monosymptomatic nocturnal enuresis

### Acronym
SToPMNE

### Study objectives
We aimed to investigate if there was any relationship between screen time and the severity of primary monosymptomatic nocturnal enuresis and treatment success

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 05/03/2021, Afyonkarahisar Health Sciences University Clinical Research Ethics Committee (Dörtyol, 2070. Sokak NO:3/4. 03030 Afyonkarahisar Merkez/Afyonkarahisar, Turkey; +90 272 246 33 01; klinikarastirmalar@afsu.edu.tr), ref: 2011-KAEK-2/198

## Study design
Interventional randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Primary monosymptomatic enuresis

## Interventions
1. After a diagnosis of primary monosymptomatic nocturnal enuresis, classified as mild (1-2 wet nights/week), moderate (3-5 wet nights/week) and severe (6-7 wet nights/week), patients were separated by the amount of screen time:
Group 1. < 120 min mean screen time/day
Group 2. > 120 min mean screen time/day
2. For treatment response, patients were randomly assigned to treatment:
Group 3. Patients were administered 120 µg desmopressin melt (DeM) and, in addition to supportive treatment, were requested to reduce daily screen time to < 60 mins
Group 4. Patients were given 120 µg DeM and supportive treatment was recommended with no restriction of screen time
3. Patients who reduced their screen time to less than 60 minutes were followed for 3 months.
4. Patients without recurrence, defined by one or more night-time bed wetting events in month 4, received further recommendations and terminated the trial.
5. Patients with recurrence were re-evaluated and treatment was planned. Treatment of other patients who did not benefit from treatment and behavioral adjustments continued.
6. The groups were statistically compared in respect of descriptive data, response to treatment, and recurrence.

## Intervention Type
Behavioural

### Primary outcome measure
Treatment response measured by the dryness of a child’s sleeping quarters recorded daily on waking, defined as a full response at 100% dryness, a partial response at 50-99% dryness, or a failure at <50% dryness at month 3. Patients in groups 3 and 4 with a full response had their DeM treatment terminated and recurrence, defined by one or more night-time bed wetting events in month 4, was determined at a follow-up visit at the end of month 4.

### Secondary outcome measures
Late recurrence, defined by one or more night-time bed wetting events from month 4 and measured daily on waking, was recorded at a 6-month long-term follow-up visit.

### Overall study start date
01/02/2021

### Completion date
15/10/2021

## Eligibility

### Key inclusion criteria
1. Aged 6 to 18 years
2. Diagnosed as primary monosymptomatic enuresis nocturna as a result of history, physical examination and routine tests
3. Have not had an operation due to urinary system pathologies before
4. A body mass index below the 95th percentile
5. Screen exposure of different durations
6. Caregivers or patients who can keep a voiding diary, nighttime bedwetting chart

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
6 Years

### Upper age limit
18 Years

### Sex
Both

### Target number of participants
75

### Total final enrolment
71

### Key exclusion criteria
1. A diagnosis with secondary enuresis and non-monosymptomatic nocturnal enuresis
2. Previously treated for nocturnal enuresis
3. Neurological disease, obstructive respiratory diseases and diabetes mellitus
4. Previously diagnosed neurogenic bladder, vesicoureteral reflux, urinary system stone disease
5. Previous surgery due to urinary pathology
6. A body mass index above the 95th percentile
7. Caregivers or patients who cannot keep a voiding diary, nighttime bedwetting chart

### Date of first enrolment
15/03/2021

### Date of final enrolment
15/06/2021

## Locations

### Countries of recruitment
Türkiye

### Study participating centre
**Afyonkarahisar Health Sciences University**
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## Sponsor information

### Organisation
Afyonkarahisar Health Sciences University

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### Sponsor type
University/education

### Website
https://afsu.edu.tr/

## Funder(s)

### Funder type
Other

### Funder Name
Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer- reviewed journal

### Intention to publish date
01/07/2022

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon reasonable request from Hacer Gizem Gerçek, gizem.gercek@afsu.edu.tr

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 17/02/2023 | 22/02/2023 | Yes | No |