Novel digital technology supporting sun protection and vitamin D synthesis by using satellite-based monitoring of spectral solar radiation

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MEDCIN DERMATOLOGIA

SIHEALTH Sensing & Intelligence for HealthCare

BASF We create chemistry

Conflicts of interest

- Antony R Young received a consultancy fee paid by siHealth and BASF, including his travel to Brazil and accommodation costs.
- Sergio Schalka, the Clinical Director of Medcin, received a consultancy fee paid by siHealth and BASF for logistics organisation and clinical supervision
- Emilio Simeone, Marco Morelli and Rowan Temple are respectively the CEO, the CTO and the Head of Technology Innovation of siHealth
- Myriam Sohn and Christina Kohlmann are employees of BASF, that provided the study sunscreens

Background

- Solar UVR exposure has risks and benefits
- Hard for individuals to determine optimal solar exposure times because of multiple factors such as:
  - Ultraviolet index (UVI)
  - Skin type
  - Sunscreen use
  - Body surface area exposed
- Apps may be an important health tool but not typically based on real-time UVR data

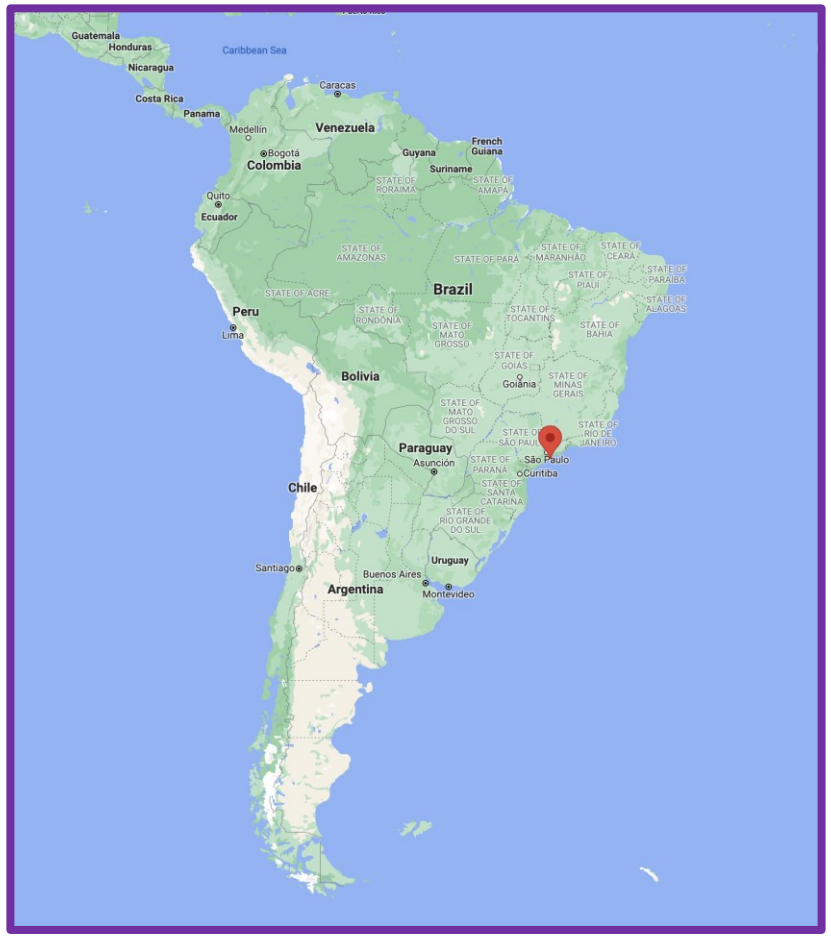
Study aim

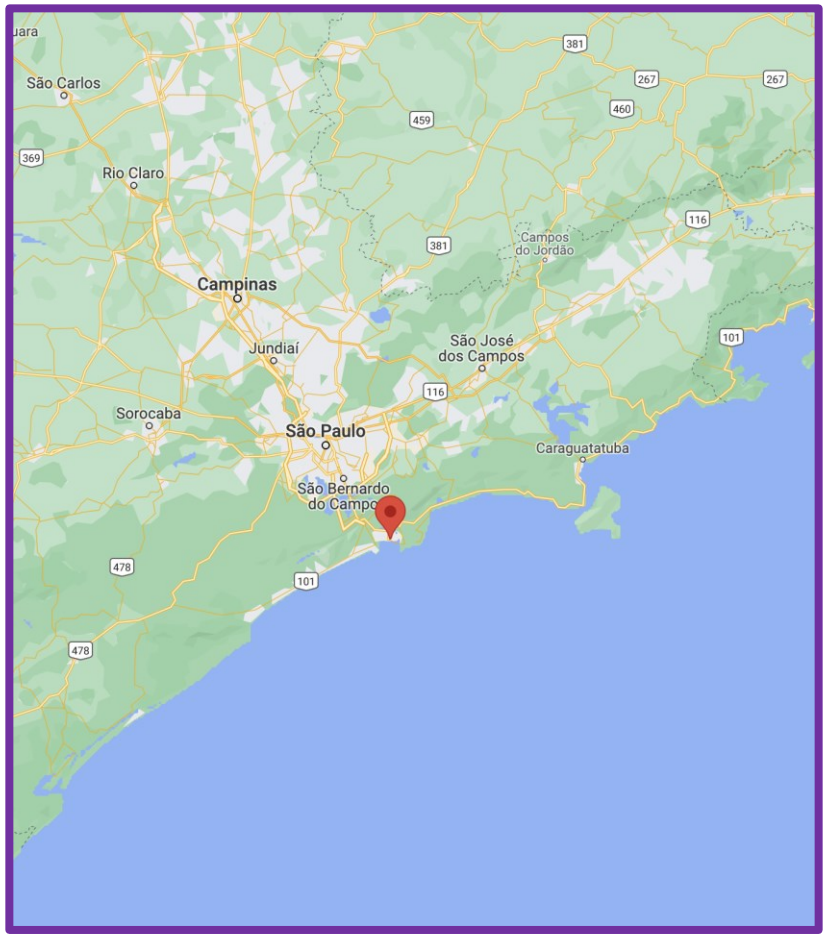
- Evaluate a new app [Sun4Health® by siHealth Ltd (Oxfordshire, UK)]
  - Real-time satellite-based spectral UVR data
  - Based on a siHealth's patented technology (Patent no. WO 2017/153832)
  - Personalised data input (e.g., personal MED calculated from user profile)
  - Incorporates spectral properties of any sunscreen
  - Personalised advice to balance the benefits and risks of solar exposure
  - Personalised recommendations on sunscreen quantity and on its re-application
  - Creates personalised 3D avatar that provides body-site specific recommendations to avoid sunburn (Sun4Health®-3D version, connected to a wearable device)
- Short break high UVI beach holiday

Study design

- Period
  - 6-8th and 13-15th December 2019 (long weekends)
- Location
  - Santos, Brazil (23.97^{o}S, 46.33^{o}W)
- Volunteers
  - N=59, 18-50 years, Fitzpatrick skin types (FST) I-III
- 3 app option groups (control, Sun4Health®, Sun4Health®-3D)
- Sunscreens provided by BASF
- Erythema and vitamin D status monitored every day

Santos, Brazil

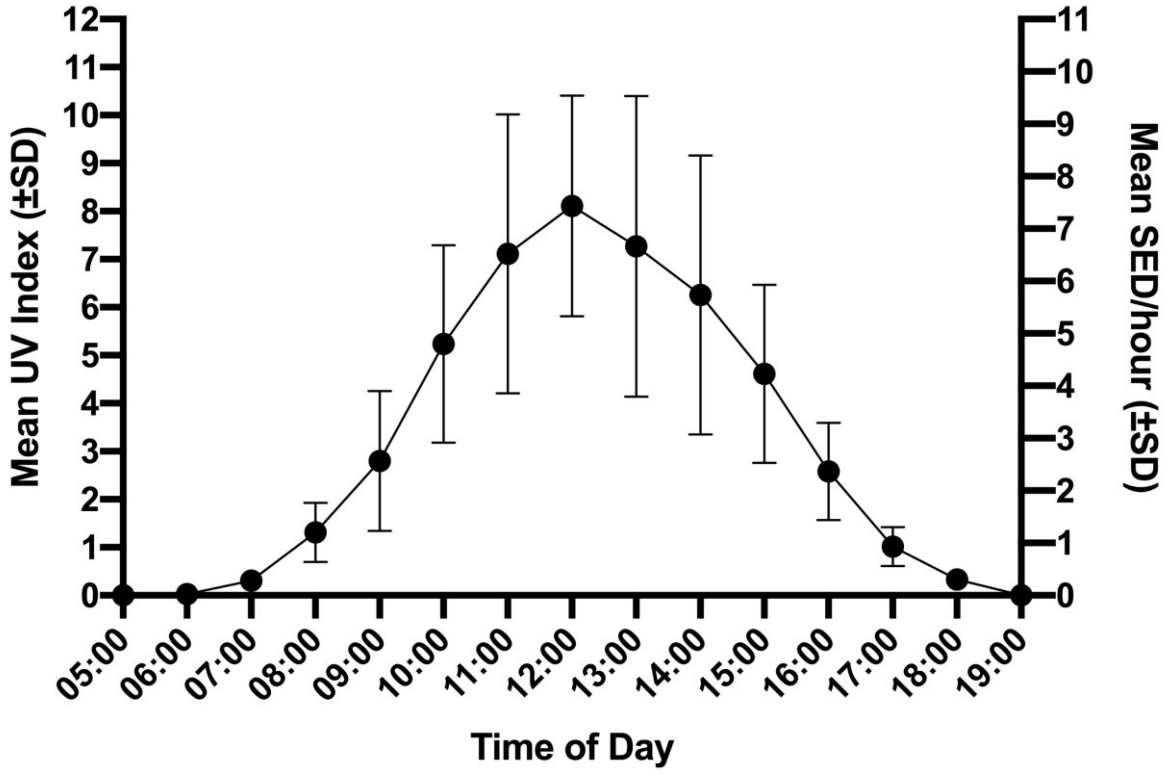




Ground-based solar UVR measurement

- Hotel roof with no shadow
- SUV-E UVR radiometer calibrated for erythemally effective irradiance
- Sampling every second and data archived as mean values per minute and transmitted to a cloud via a dedicated datalogger
- Data used to assess the validity of the satellite based UVR monitored by the Sun4Health® app

Mean daily UVI and ambient SED



Sun4Health® app's functionalities

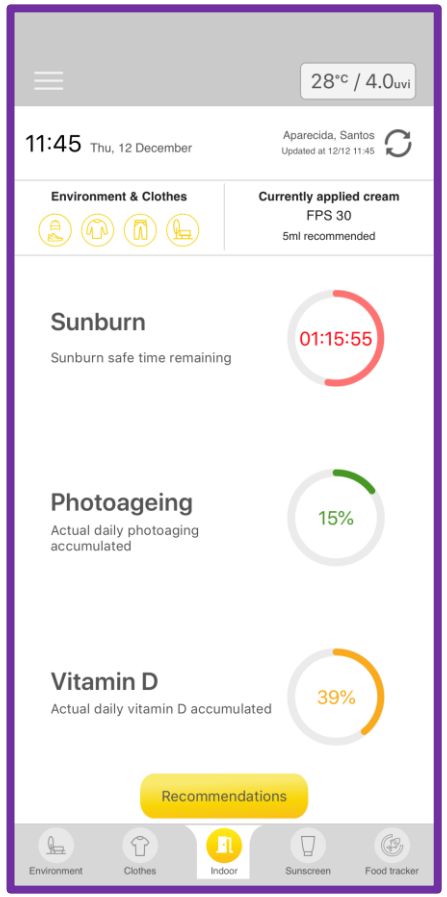
- Questionnaire to estimate user's minimal erythema dose (MED)
- Real-time satellite-based monitoring of erythemal and vitamin D-effective irradiances (CIE action spectra)
- Input data
  - Sunscreen
  - Clothing
  - Environment
- Remaining "safe" exposure times based on 0.7 MED as "100% erythema risk"
- Real time dosimetry of accumulated daily effective vitamin D dose and remaining time to reach "100% vitamin D daily target" (assuming equivalent of 400 IU or 10 µg/day as daily target)

App options (randomly assigned)

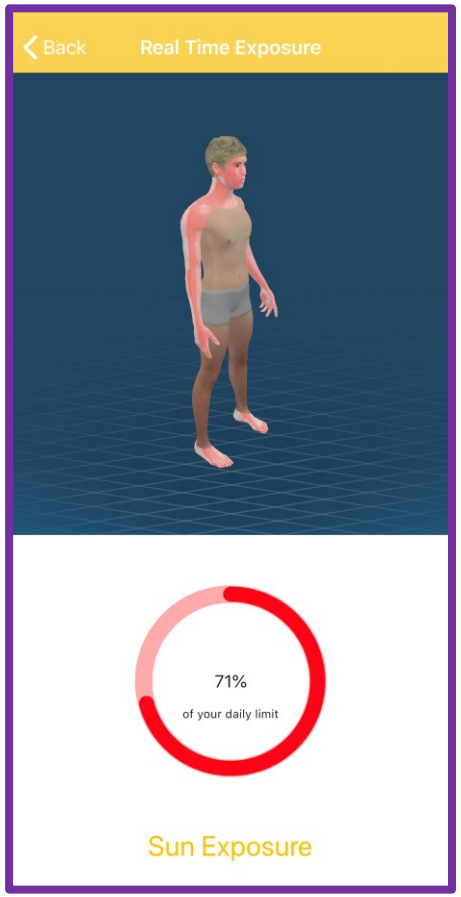
- **Group 1:** Control app
  - UVI only (commonly available weather information), with no specific personalised recommendations
- **Group 2:** Sun4Health® app
  - All functionalities of Sun4Health® (without 3D wearable device)
- **Group 3:** Sun4Health®-3D app
  - All functionalities of Sun4Health® plus wearable device for 3D dosimetry

Sun4Health® app's versions

Sun4Health®
(Group 2)



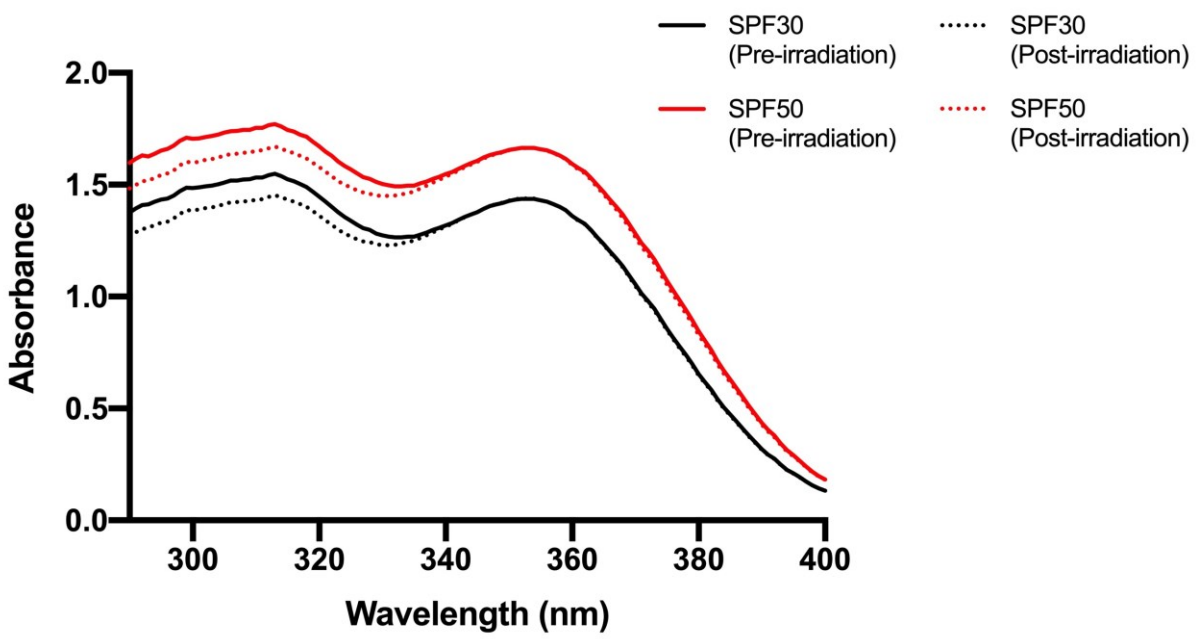
Sun4Health®-3D with wearable device
(Group 3)



Bluetooth®

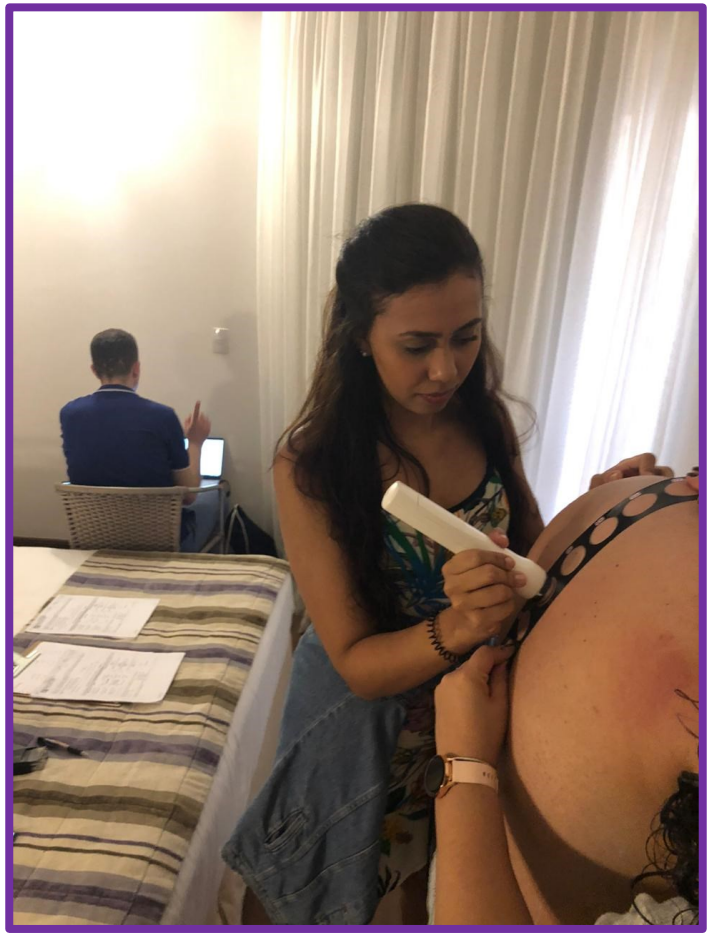
Sunscreens

- Provided by BASF
- Range of cosmetic formulations
  - SPF = 30, UVA-PF = 12.4
  - SPF = 50, UVA-PF = 19.4
- Volunteers had free choice
- Used freely by all the groups (groups 1, 2 and 3)
- Instructions given on optimal use only via the Sun4Health® app (i.e., to groups 2 and 3)
- Sunscreen use weighed



Erythema assessments

- Reflectance spectroscopy (Mexameter® MX MX18WL by Courage + Khazaka Electronic GmbH, Germany)
- Six body sites
  - Right underarm (control)
  - Right and left shoulders
  - Back
  - Right and left abdomen
- Every morning and every afternoon
- Change over whole study period used for data analyses



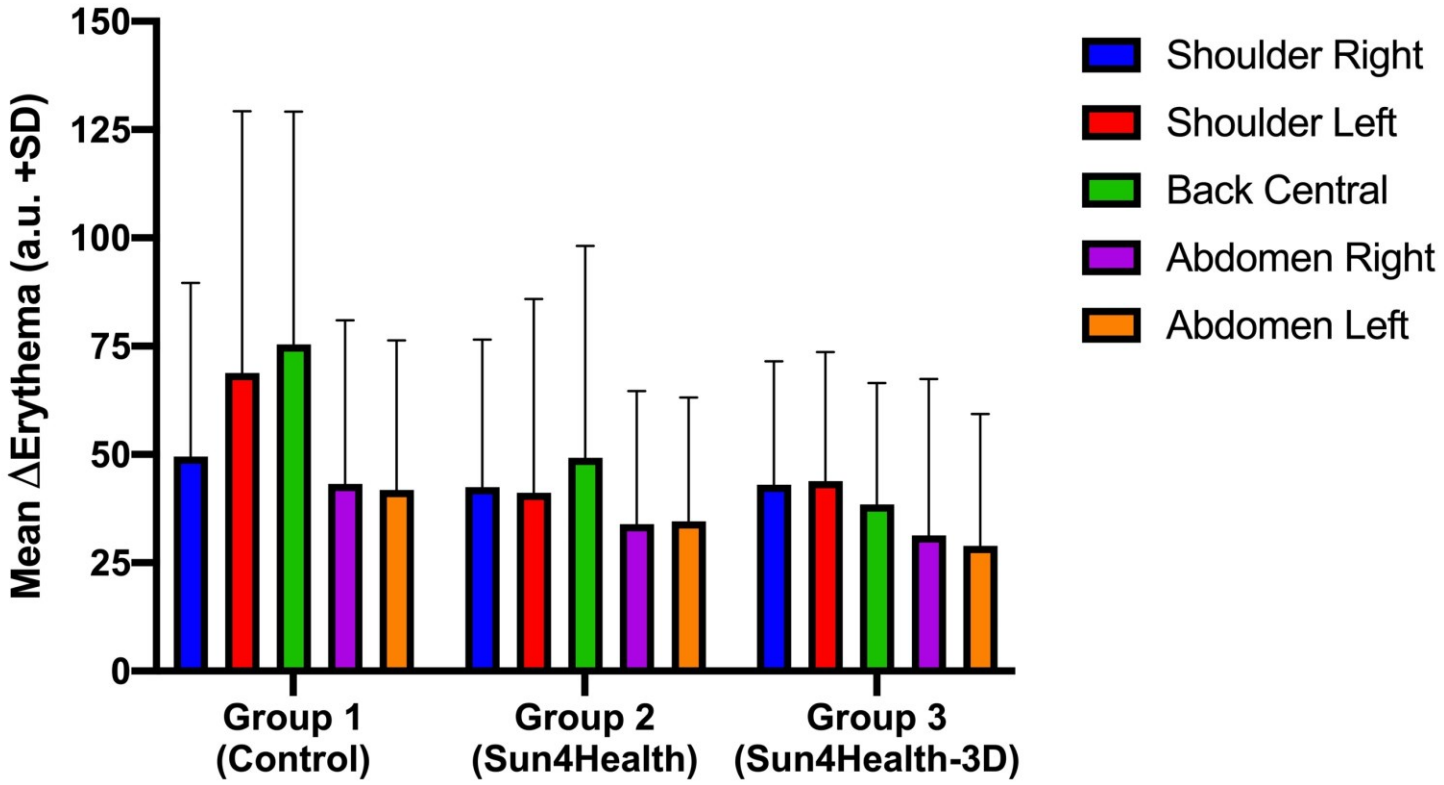
Vitamin D status

- Blood samples taken 1 day before study and 3 days after (managed by Instituto de Análises Clínicas de Santos, Brazil)
- HPLC tandem mass spectrometry for $25(OH)D_2$ and $25(OH)D_3$

Time outdoors, sunscreen use and UVR exposure

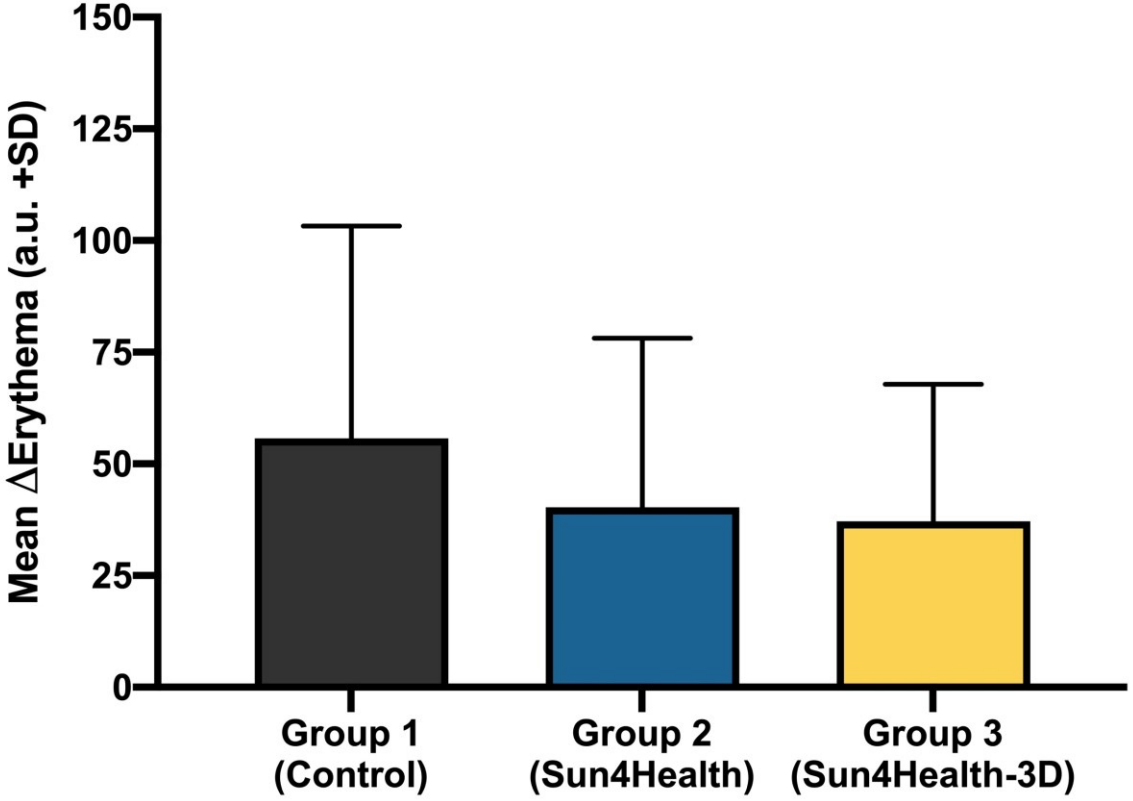
App group	All Fitzpatrick Skin Types									
	Time outdoors (h)		Total SS use (g)		Average SPF		Total SED		Est. total SED through SS	
	Mean	± SD	Mean	± SD	Mean	± SD	Mean	± SD	Mean	± SD
1	13.03	3.1	73.77	40.7	43.7	19.1	67.56	8.02	1.63	0.6
2	12.73	3.3	49.23	33.6	41.6	9.6	66.47	13.01	1.68	0.8
3	12.72	2.3	60.12	41.0	42.3	9.0	67.52	8.43	1.70	0.7
All groups	12.82	2.9	60.82	39.2	42.5	9.3	67.18	9.94	1.67	0.7

Δ erythema over 3 days for each body site



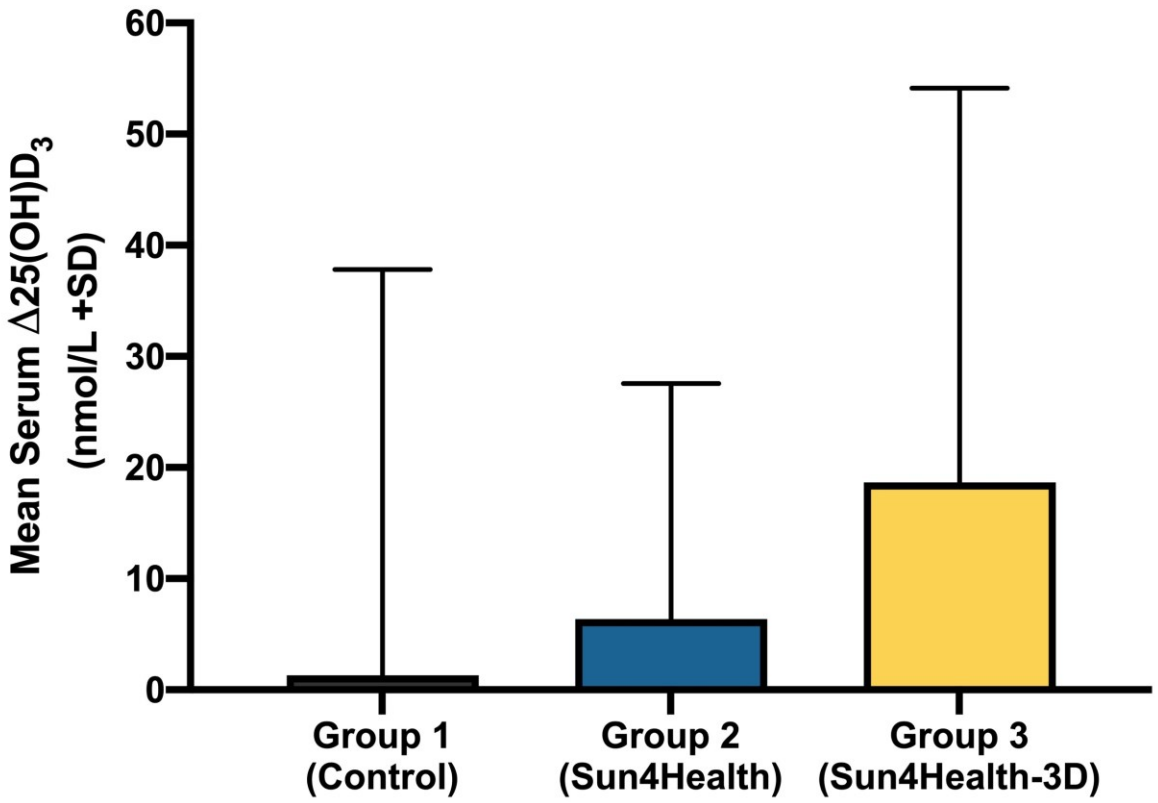
Δ erythema over 3 days for all body sites combined

- ANOVA P < 0.05
- *Post hoc* comparisons
  - Group 1>2 (P = 0.01 or 0.03 after Bonferroni correction)
  - Group 1>3 (P= 0.001 or 0.003 after Bonferroni correction)
  - Group 2=3 (P >0.5)
- Sun4Health® app reduced total body cumulative erythema



Mean difference in vitamin D status

- Serum 25(OH)D_2 was below the limit of detection (12 nmol/L) in all cases
- Change in serum 25(OH)D_3
  - ANOVA P > 0.05
  - Group 3>2>1
- The use of the Sun4Health® app increased serum 25(OH)D_3 , but with high interpersonal variation



Study strengths and weaknesses

Strengths

- Clinical field study
- High UVI
- Direct monitoring of participants

Weaknesses

- Limited sample size
- Short duration
- Participants in close contact and may have influenced each other
- Weather cloudier than expected for season

Conclusions

- The Sun4Health® app (groups 2 and 3) significantly reduced skin erythema (sunburn risk) compared to control group 1
- The recommendations provided by the Sun4Health® app (groups 2 and 3) have resulted in an increase of the mean serum 25(OH)D_3 level compared to control group 1, but the high interpersonal variation implies that further studies are needed
- Overall, the results show that the digital Sun4Health® app providing real-time advice is safe to use and can modify behaviour to reduce skin erythema (sunburn) under very high UVI (e.g., from beach activities), yet increasing the level of vitamin D synthesis

Research team and volunteers

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Acknowledgements

- The clinical field study (No. RBR-2MF6QG) was registered on 20th May 2020 with Registro Brasileiro de Ensaios Clínicos (ReBEC), with ethical approval EN19-0771-01 received by the Brazilian Ministry of Health (CONEP)
- The study was co-funded by siHealth, by BASF and by the European Space Agency (contract no. 4000120541/17/NL/US)
- The authors ARY, SS, MM and ES have been the co-Investigators of the study
- The authors are grateful to the volunteers, to the siHealth team that developed the apps, to Markus Schwind and Anja Suckert from BASF for their support
- The siHealth's Sun4Health® app is distributed as "Sun3P" ("Sun3P-3D" in its 3D version) and commercialised by BASF in the personal care market for providing personalised products